GENORAY

Fluoroscopic X-ray System

ZEN-7000

User's Manual

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1. Introduction and Safety

1.1 Introduction

This manual is for using ZEN-7000 safely. ZEN-7000 should be used by experienced users only.

X-Ray machine and electric medical equipment have potential risk. All users must be fully aware of all safety details such as emergency situation, and how to use.

Users must be aware of self protection from potential risks, and must recognize of the condition of the equipment which might occur hazards.

Manufacturer, assembler, and importer have responsibility for safety and confident of this machine and below matter.
- Guarantee authorized person only install, calibrate, and fix.

Genoray Co.,Ltd. develops equipments continually. Manual and specifications subject to change without notice

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1.2 Intended Use

ZEN-7000 is a mobile fluoroscopy system is designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.

1.3 Certificate of Warranty

1.3.1 Range and terms for warranty

Genoray guarantee this product without any expense for the mal-function or disorder occurred under standard transportation and operation within 1 year from installation.
Defect on its appearance is our of the range of warranty.

1.3.2 Requirements on after service call

When the malfunction or disorder appeared, stop operating and check again the related article of this "User's Guidebook." Before your calling, please put off this equipment and check for the Model Name, serial No. and purchasing date.
Genoray Co., Ltd. is not responsible for indirect harm.
Genoray Co., Ltd. cannot warrant for defect or harm after warranty period.

1.4 Symbols

SYMBOLS	Description
	X-Ray Source Assembly, X-ray radiation
	Caution! Refer to the user's manual
	Type b applied part
	Electric shock danger
	WEEE Mark
	Laser

This symbol is information about the special matters that require attention while using this software.

This symbol is attention the situation or environments which might bring danger to the patients or users.

This symbol is danger the situation or environments which might bring danger to the patients or users.

1.5 Check before use

① Check connecting condition of switch, polarity, dial, meta, and if the machine works well.
② If ground connection is connected well.
③ If every connections of codes are correct and safe.
④ Using this machine with other equipments has possibility of wrong diagnose or accident. If there is a problem, please ask manufacturer.
⑤ Recheck outside circuit connected to patient directly.

1.6 Electricity safety and fire

Electric circuit of this product has high voltage which can cause serious injury or electrocution. Do not cover any of product to avoid this dangerous situation.

Be fully aware of below safety regulations to avoid dangerous situation for user or patient
- If you'd like to clean this product, turn off and plug out, then clean with moistened cloth or sponge.
- Do not open cover for any situation, let experienced technician from Genoray open for you.
- Do not put food on any part of this product. This could contact conductivity material in electric circuit.

This product is not waterproof. If liquid comes in this product, electric short circuit or fire might be occurred. If liquid is spilt by accident, do not touch power code, just leave the product before the liquid is dried.

Please follow below directions at an emergency
- Turn off the machine and plug out the power cable from socket.
- Stay away from the product.
- Call for help.
- Use fire extinguisher only for the fire caused by electricity.

Wrong type of fire extinguisher might cause electric shock or scald. Check the right type before use.

1.7 Power Requirements

Before power is connected to the system, the operator must be certain that the power outlet has been approved, as indicated below, for the current, voltage, and line regulation requirements of the system.

Note: A dedicates AC power line is recommended to avoid conflicts with the power requirements of other equipment.
Check if right source of electricity is supplied in the spot to install this product.

Line Voltage	:	AC220-230V, 50/60 Hz AC100-120V, 50/60 Hz (USA)
Line Phase	:	Single
Line Code	:	5m
Power capacity	:	4kVA
Over-current releases	:	250V, 50/60Hz, 20Amp.
Apparent resistance	:	0.2 ohm
Classification	:	Class I, Type B

Check the power supply line is right to the machine. Connect power cable of the machine to power socket after checking source of electricity.
Above checking should be done when power is input to all the accessories(and signal input and output)

AC source of electricity for exclusive use is recommended to avoid discord with other equipment's needed source of electricity.

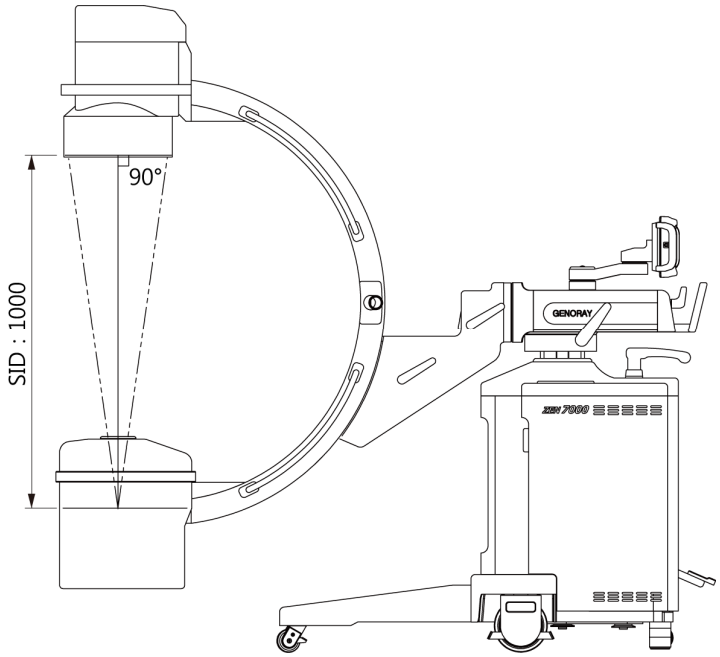
Keep this product away from source of electricity generator, other X-Ray products, and base station of broadcast. Abnormal image can be output if the product shares source of electricity with other electricity or electronic products.

1.8 Suitability of electromagnetic waves

This equipment has been tested and found to comply with the limits for medical devices in EN 601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

1.9 Focus and tolerance between the focus and datum axis.



The angle between the reference axis and the image receptor plane is 90°

1.10 Safe use of Radiation

Wearing radiation proof equipment for all users should be guaranteed to use this product.

This X-Ray machine could be dangerous for patient, if user doesn't follow right steps of operation.

1.11 Scatter Radiation

The scatter radiation was measured in the distance of 1m at various angles according to IEC 60601-1-3.
And Genoray test data of scatter radiation is complied the limit of above standard.

The range of X-ray scatter of this device is a radius of more than 2m. User should stay away from this device farther than 2 meters when X-Ray is on exposure.

1.12 Cleaning and User environment

Clean operation panel and other surfaces softly with moistened soft cloth.
Please avoid below environment.

- Moisture
- Direct ray of light
- Dirt
- Anti-Ventilation
- Salty air
- Chemistry, Harmful gas

Please keep the product away from environment with strong vibration, or higher temperature or humidity

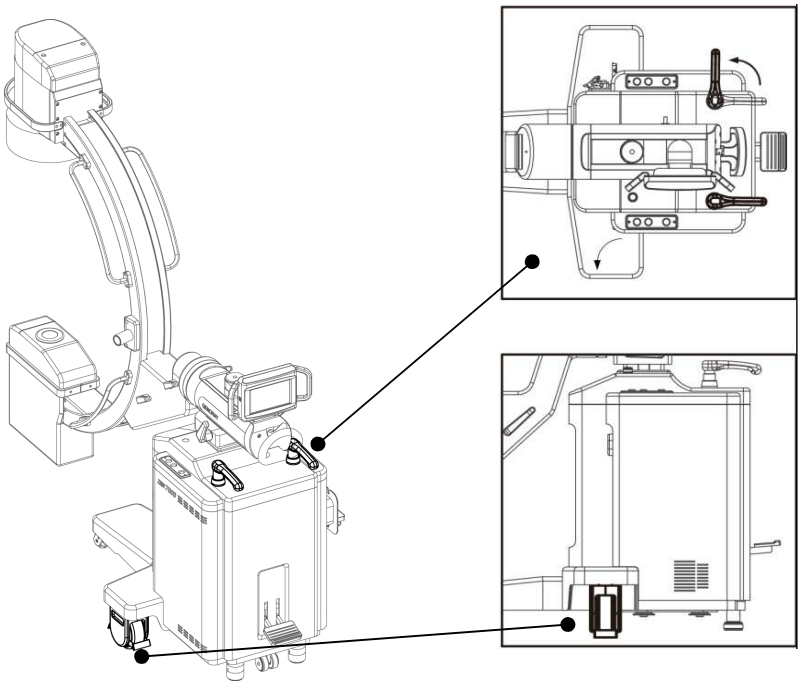
- Environment for movement or Storage
  Temperature : -40°C ~ 70°C
  Relative humidity : 10% ~ 95% RH
  Air pressure : 50 ~ 106 kPa

- Environment for using
  Temperature : 10°C ~ 40°C
  Relative humidity : 30% ~ 75% RH

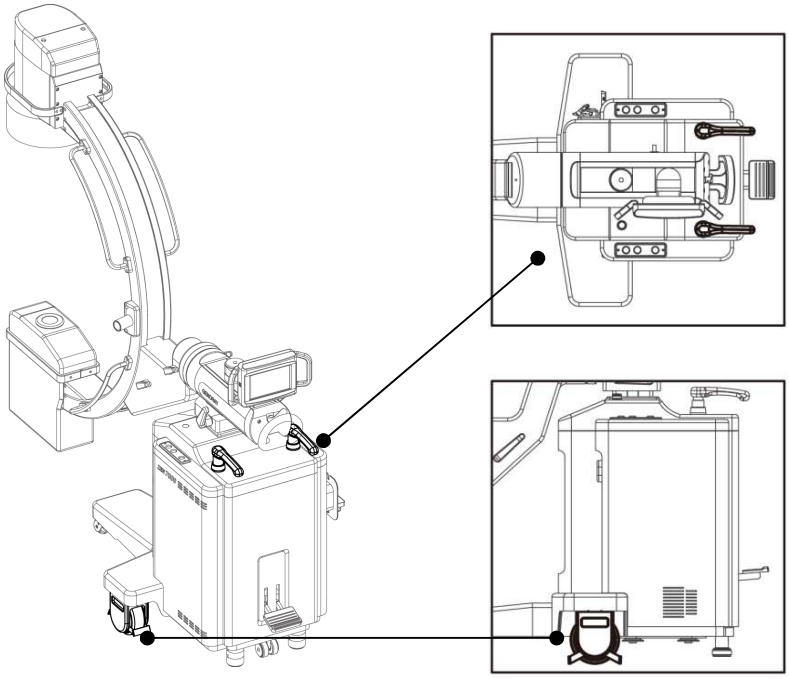
1.13 Movement

The product can be moved as below.

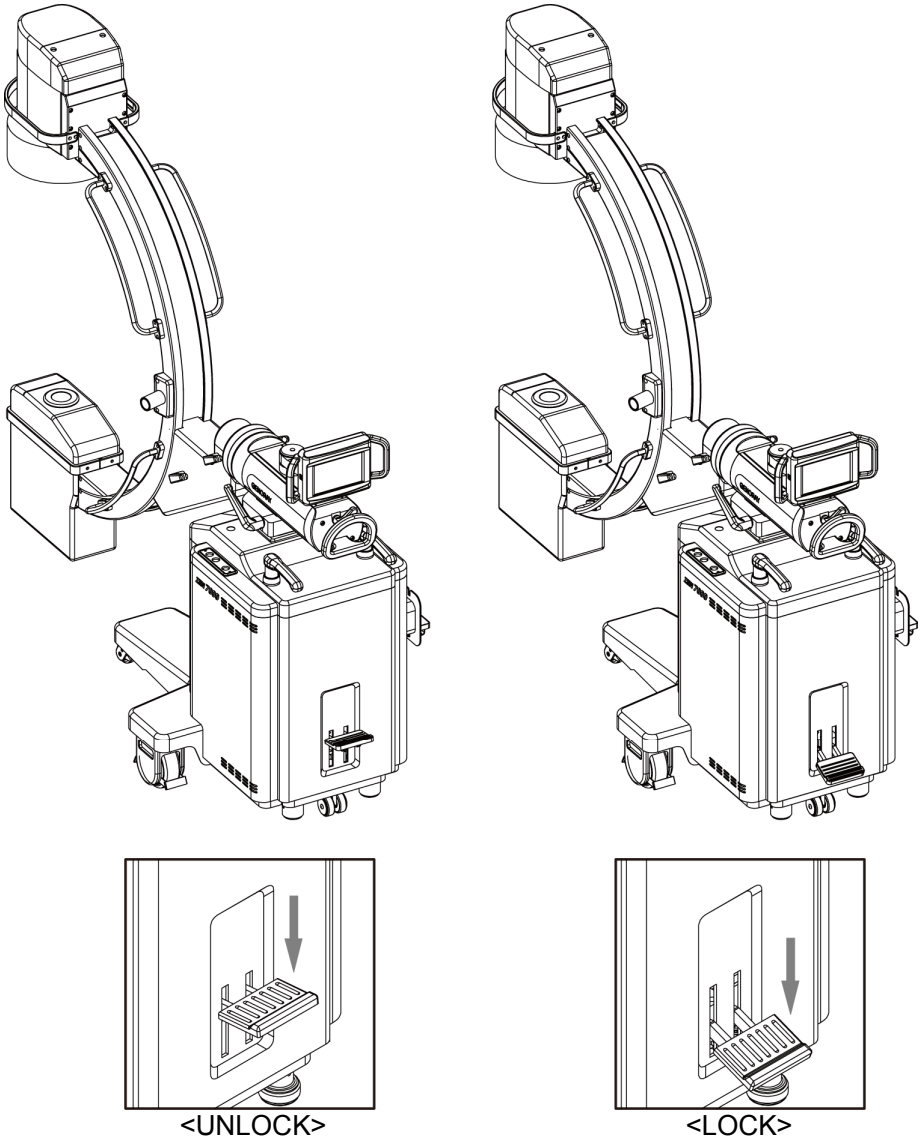
(1) Left/Right movement
Control the handle as below.



(2) Forward/Backward movement
Control the handle as below.



(3) Lock steering
Step the brake pedal to fix machine.



<UNLOCK> <LOCK>

Check the source of power of the spot to go before moving the product.

Call to Genoray if you find something wrong with the product after it is moved. Connector of board in the product might be disconnected.

1.14 Overheated

Temperature of high voltage generator.

Normal Temperature 10□ ~ 54□ Green => X-RAY can be shot

Normal Temperature 55□ ~ 59□ Yellow => X-RAY can be shot
(Generator might be overheated)

Normal Temperature 60□ ~ more Red => X-RAY cannot be shot
(Generator overheated)

Turn off the product and leave it for 2~3 hours when the red signal comes, then temperature is going to normal. Turn on the power and check the condition of the product.

1.15 The heat dissipation

The cooling condition requirements for safety operation include information concerning the heat dissipation during normal use : the maximum heating dissipation of ZEN-7000 is 750 W (225kJ(300kHU)), the minimum distance 50cm between the x-ray room wall and the ZEN-7000 should be guarantee to make sure the good dissipation condition of ZEN-7000

1.16 The mode of operation

The mode of operation – where appropriate, together with maximum permissible ratings : continuous with intermittent X-ray loading

- 60kV, 3mA
- Loading Time : 1 min
- Waiting Time : 10 min

This device should have wait time of 10 Minute after two exposure for protection of tube.

Continued use without cooling may damage that X-ray tube and gives extremely high temperature on the tube assembly.

1.17 Mechanical Trouble in ZEN-7000

While using the product, if the circuit breaker has been broken off after the reset, it means it is having the mechanical trouble. In this case, do not try to operate the machine, and contact the manufacturer.

If at any case the other functions of this product does not operate the way it is supposed to operate, refer to the solution listed below

1. Do not operate the product.
2. Turn off the power of the product.
3. Contact the manufacturer immediately.
4. Until you hear from the technician of manufacturer, do not operate the product.

1.18 Accessories

The accessories delivered with the basic configuration of the ZEN-7000 consist of :

- Cassette Holder (Option)
- Consolidated Manual
- Foot Switch

The detachable parts and materials, if the use of other parts or materials can degrade minimum safety.

Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529: IPX0, ordinary equipment with foot switches (IPX8).

It is possible adverse effects arising from materials located in the X-ray Beam.

1.19 Disposal of waste matter

In case of disposal including the equipment, follow the nation’s regulation.
Please follow the regulation applied in the country of use.

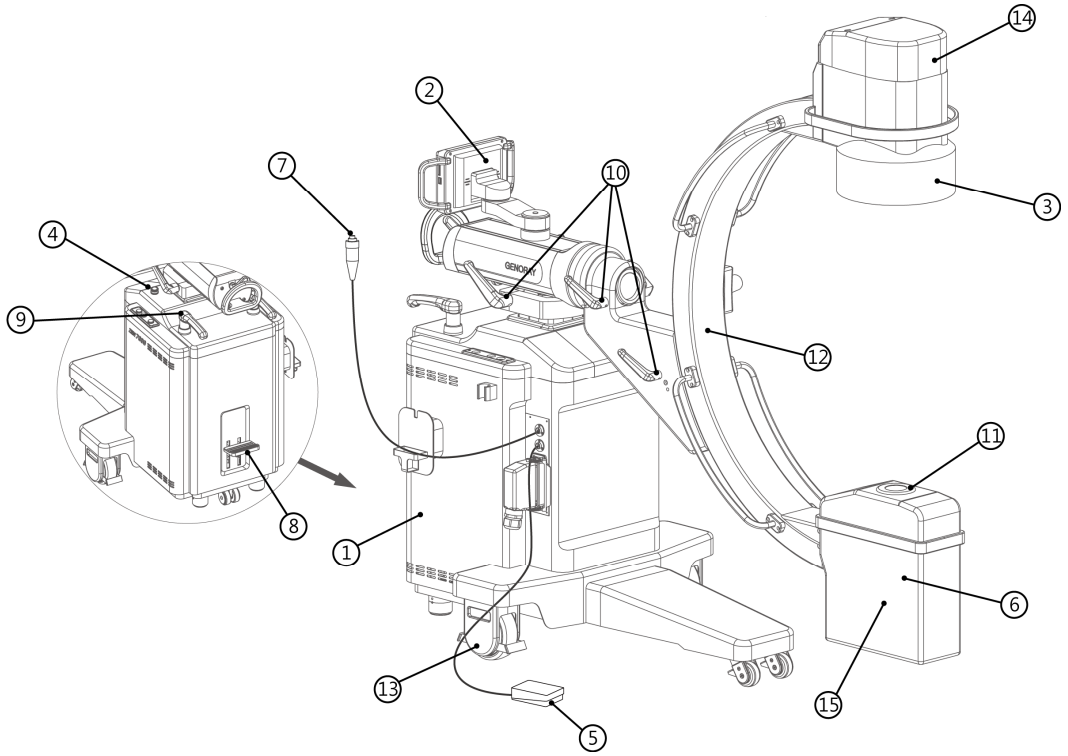
The European economic organization required the appropriate recycling or waste according to the environment on regulation of electric equipment on 2002/96/EG(WEEE)

1.20 lifetime of the device

The life time of the ZEN-7000 is 10 years in the normal conditions of use.

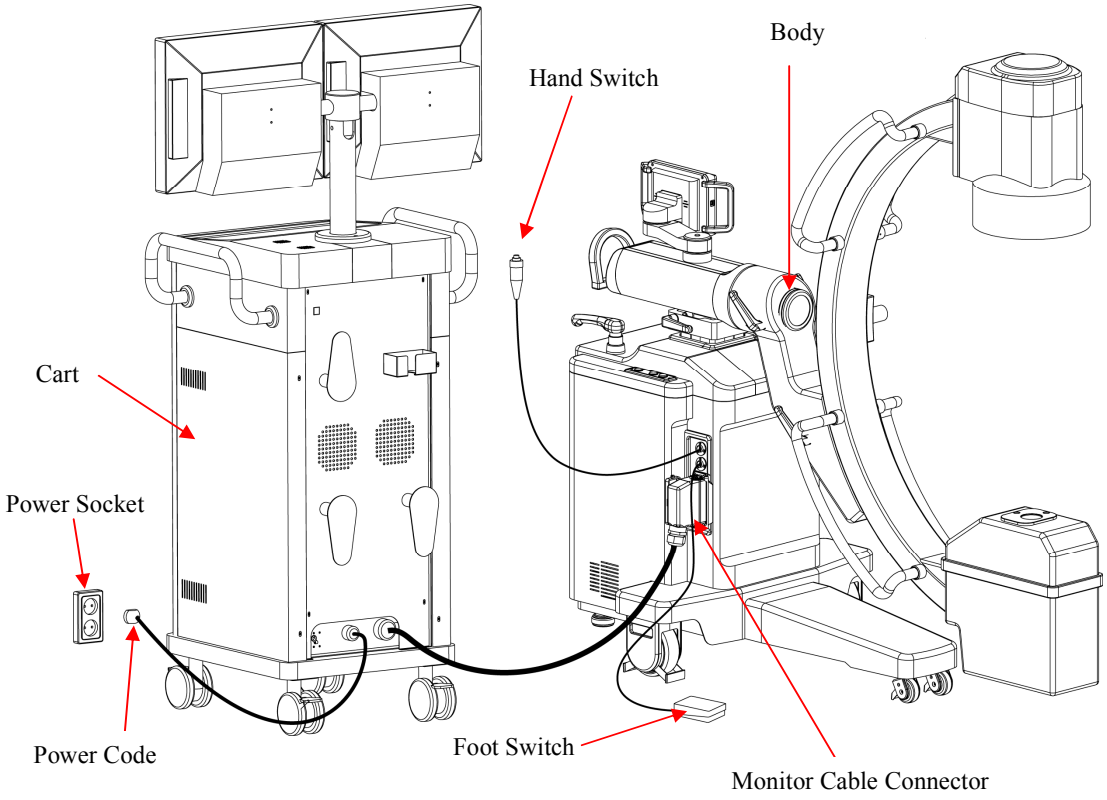
2. Component

2.1 ZEN-7000 Main body

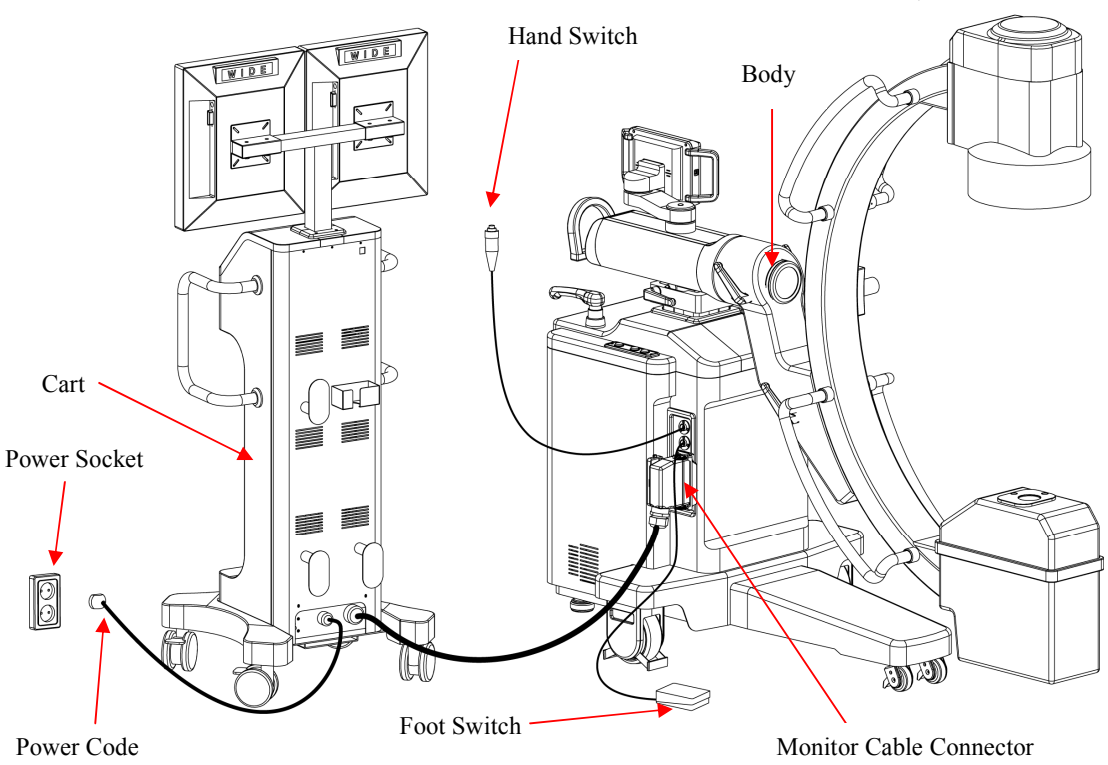


1	X-Ray support part	9	Control Handle
2	X-Ray control part	10	Fixed Lever
3	I.I	11	X-Ray Collimator
4	EMERGENCY Switch	12	C-ARM
5	Foot Switch	13	Wheel
6	X-Ray Generator	14	XTV Camera
7	Shooting(Hand) Switch	15	X-ray tube
8	Brake		

- Cart Option 1)



- Cart Option 2)



2.2 Shooting Switch(Hand switch)

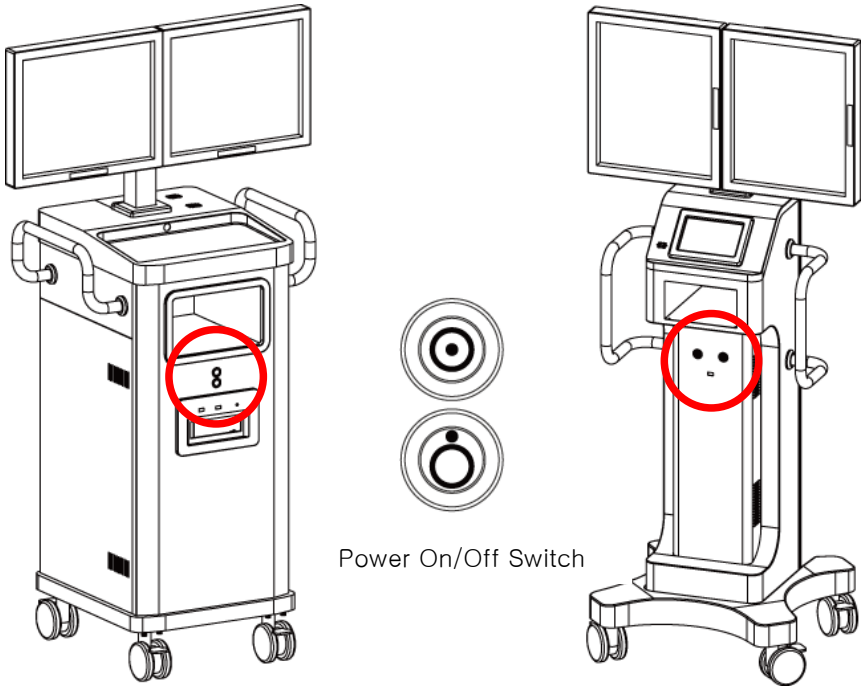
This is used for shooting X-Ray at fluoroscopy and radiography mode. X-Ray will be irradiated immediately when you press the shooting switch, because tank is always ready for irradiation. However, you should press ready button for 5 seconds ( ) then press shooting switch and X-ray will be irradiated.

2.3 Power On/Off Switch

On/Off switch is on centre of the cart. Product tests itself for few seconds after X-Ray control part is turned on when user turns on power.

To use ZEN-7000

1. Connect power cable of the product to power socket.
2. Product is turned on when press green button of power switch for 1 second.
(Lamp of power switch is turned on when main circuit brake switch is turn ON)



Cart Option 1)

Cart Option 2)

3. X-Ray Controller(Operation Panel)

Control X-Ray tube input and shooting condition.

< X-Ray Controller >

3.1 Condition Display

Present condition of the machine

3.1.1 Ready and Wait

Disable

Waiting

Going to be ready: Flickering

Ready

3.1.2 X-RAY Shooting condition

OFF

ON

3.1.3 X-ray Shooting mode

Radiography

Fluoroscopy

Pulsed Fluoroscopy

3.1.4 Temperature

Normal

Warning: « Temp Warning » is displayed on OP screen when tank temperature is 55□.

Error: Cannot shoot X-Ray when tank temperature is 60□

3.1.5 Shooting part

Hand or Foot.

Chest

Abdomen

Joint

3.1.6 Image Reversal

Normal

Horizontal Reversal

Vertical Reversal

Horizontal and Vertical Reversal

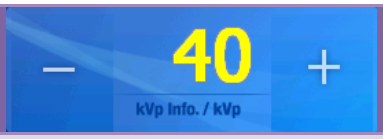
3.1.7 Message

It display the Dosemeter & Temperature

Message screen is show « Reset... » and it is changed « 0.0 » for initial of Dose meter

3.2 Basic Button

3.2.1 kVp control



Control kVp volume

3.2.2 mA/mAs control

Control mA/mAs volume

3.2.3 Manage saved image

Show saved image

3.2.4 Exposure Time

Display X-Ray exposure time. Timer for fluoroscopy. Warning sound beeps after timer shows 4 minutes, and fluoroscopy is disabled after timer shows 5 minutes.
Reset Button: Reset time

3.2.5 Accumulated time

Display X-Ray fluoroscopy accumulated time. It accumulated time 0~100 hours. It doesn't accumulate more time. Reset Button : Reset exposure time& accumulated time.

3.2.6 Save Image

Not applied	Applied	Disable

Save LIH(Last Image Hold)

3.2.7 ABC Button

Not applied	Applied	Disable

Adjust of ABC(Auto Brightness Control)

3.2.8 DNR Button

Not applied	Applied	Disable

On/Off High Mode of DNR (Dynamic Noise Reduction)
Reduce the noise to the max, even if It have afterimage

Not applied	Applied	Disable

On/Off Middle Mode of DNR(Dynamic Noise Reduction)
Reduce the afterimage to the max, even if it have Noise

Not applied	Applied	Disable

On/Off Low Mode of DNR(Dynamic Noise Reduction)
Reduce the afterimage for image of many movement, even if it have some noise

3.2.9 Focus

Small focus	Large focus	Disable

This button is can select the Small /Large Focus.
Select the small focus in the normal case. If image is not clear in 120kV & 4.0mA of small focus, can change kV & mA range in Large focus

3.2.10 ND Filter (Option)

Small focus	Large focus	Disable
On/Off ND(Neutral Density Filter)		

3.2.11 Reverse Image Button

Not applied	Applied	Disable
Reverse Image		

Below image occurs when you touch image reversal button

Back to normal	Vertical reversal	Horizontal reversal	Horizontal and vertical reversal

3.2.12 Anti clockwise rotate

Not applied	Applied	Disable
Rotate image anti clockwise		

3.2.13 Reset image

Not applied	Applied	Disable
Reset image to original		

3.2.14 Clockwise Rotate

Not applied	Applied	Disable
Rotate image clockwise		

3.3 OP Selecting Mode

3.3.1 X-ray Exposure Mode

3.3.1.1 Radiography Mode

Not applied	Applied	Disable
Radiography mode		

3.3.1.2 Fluoroscopy Mode

Not applied	Applied	Disable
Fluoroscopy Mode		

3.3.1.3 Pulsed Fluoroscopy Mode

Not applied	Applied	Disable
Pulsed Fluoroscopy Mode		

3.3.1.4 Low Pulsed Fluoroscopy Mode

Not applied	Applied	Disable

Setting x-ray exposure mode to Low pulsed Fluoroscopy Mode.

3.3.1.5 Snap Shot Button

Not applied	Applied	Disable

Exposure big amount of X-Ray at short time and save image

3.3.2 I.I Mode

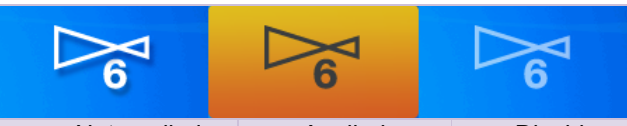
Collimator (Iris, Shutter) go initial position. (Rotaing Part not go initial position.)

3.3.2. 1 9 inch

Not applied	Applied	Disable

9 inch image intensifier mode

3.3.2.2 6 inch



Not applied	Applied	Disable

6 inch image intensifier mode

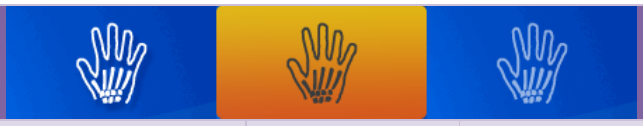
3.3.2.3 4.5 inch

Not applied	Applied	Disable

4.5 inch image intensifier mode

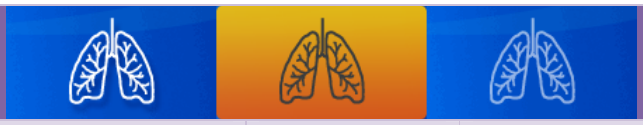
3.3.3 Shooting Part Mode

3.3.3.1 Hand and Foot Mode



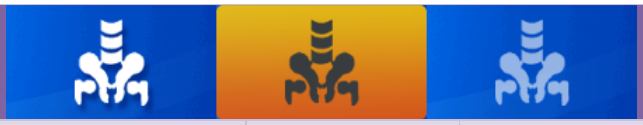
Not applied	Applied	Disable
Hand and Foot Mode		

3.3.3.2 Chest Mode



Not applied	Applied	Disable
Chest Mode		

3.3.3.3 Abdomen Mode



Not applied	Applied	Disable
Abdomen		

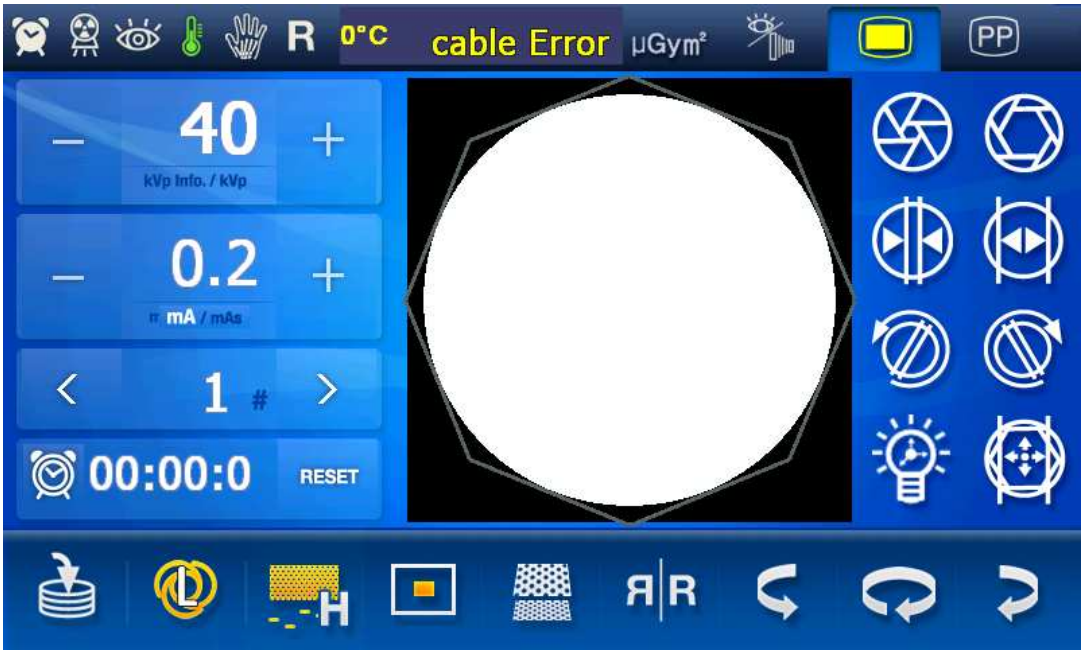
3.3.3.4 Joint Mode

Not applied	Applied	Disable
Joint Mode		

3.3.3.5 Auto Histogram.

Not applied	Applied	Disable
Auto Histogram		

3.4 OP Main Mode



3.4.1 Colimator Control

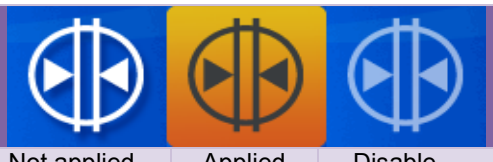
3.4.1.1 Iris Close

Not applied	Applied	Disable
Close Iris of Colimator		

3.4.1.2 Iris Open

Not applied	Applied	Disable
Open Iris of Colimator		

3.4.1.3 Slot Close



Not applied	Applied	Disable
Close Slot of Colimator		

3.4.1.4 Slot Open

Not applied	Applied	Disable
Open Slot of Colimator		

3.4.1.5 Colimator CCW

Not applied	Applied	Disable
Rotate Colimator Anti Clockwise		

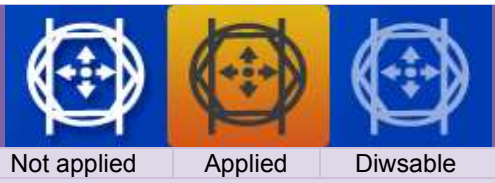
3.4.1.6 Colimator CW

Not applied	Applied	Disable
Rotate Colimator Clockwise		

3.4.1.7 Laser (Option)

Not applied	Applied	Disable
On/Off of Laser		

3.4.1.8 Initialization



Not applied	Applied	Diwsable
Initialize the position of Collimator		

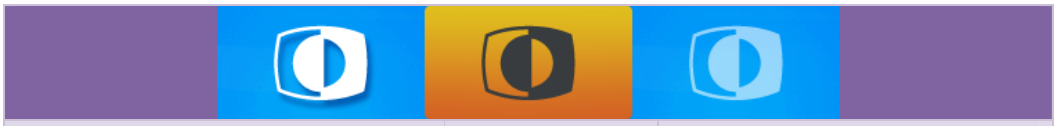
Collimator go initial position, when set up I.I mode.

3.5 OP Image Management Mode

3.5.1 Swap Button

Not applied	Applied	Disable
Change screen position of LIH(Last Image Hold) and MEM(Memory)		

3.5.2 Invert Button

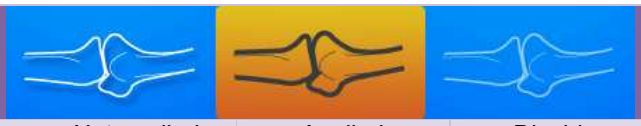


Not applied	Applied	Disable
Invert image on screen		

3.5.3 DSA Button

Not applied	Applied	Disable
On/Off of DSA(Digital Subtraction Angiography)		

3.5.4 Edge Button



Not applied	Applied	Disable
On/Off of Edge Enhancement		

3.6 DSA Mode

3.6.1 DSA Mask

Disable	Applied
Creation of DSA MASK image.	

3.6.2 Roadmap Mask

Disable	Applied
Creation of Roadmap Mask image.	

3.6.3 Remask

Disable	Applied
Restart of DSA or Roadmap	

3.6.5 Invert

Disable	Applied
Invert the DSA image & Roadmap image.	

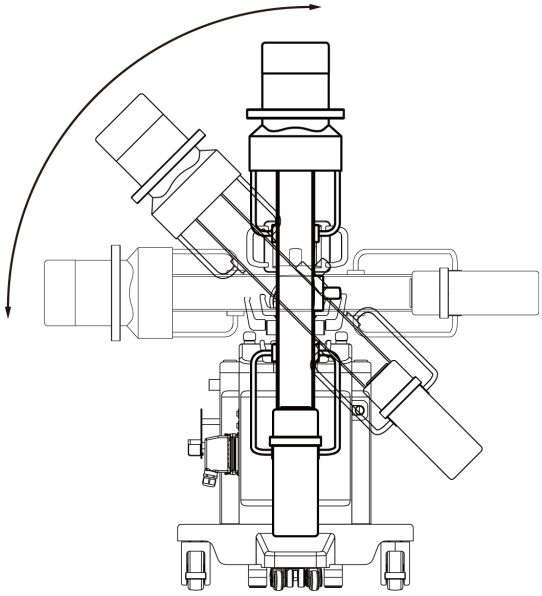
3.6.6 Close

Close the Angiography mode.

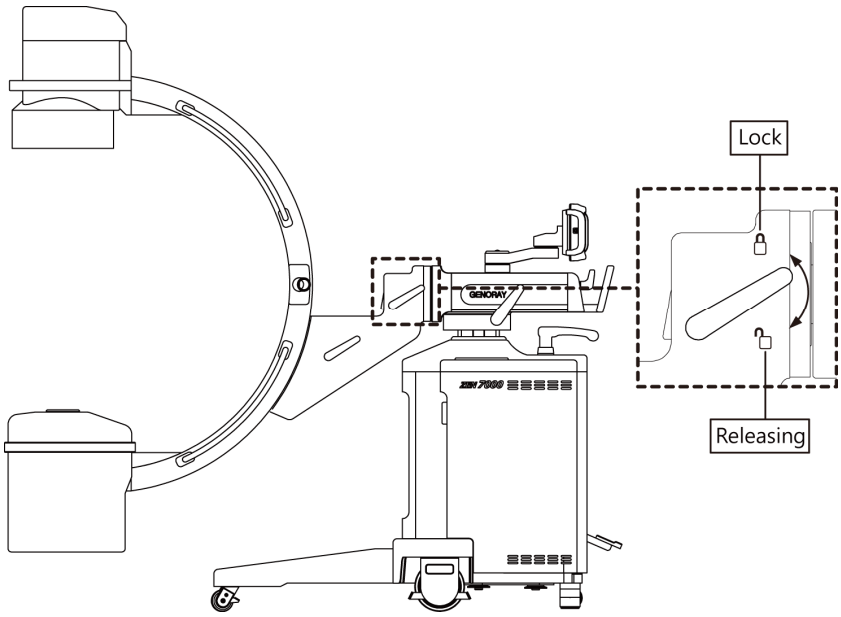
4. ZEN-7000 Motion

4.1 C-ARM Positioning

4.1.1 C-ARM Clockwise, Anti-clockwise Rotating

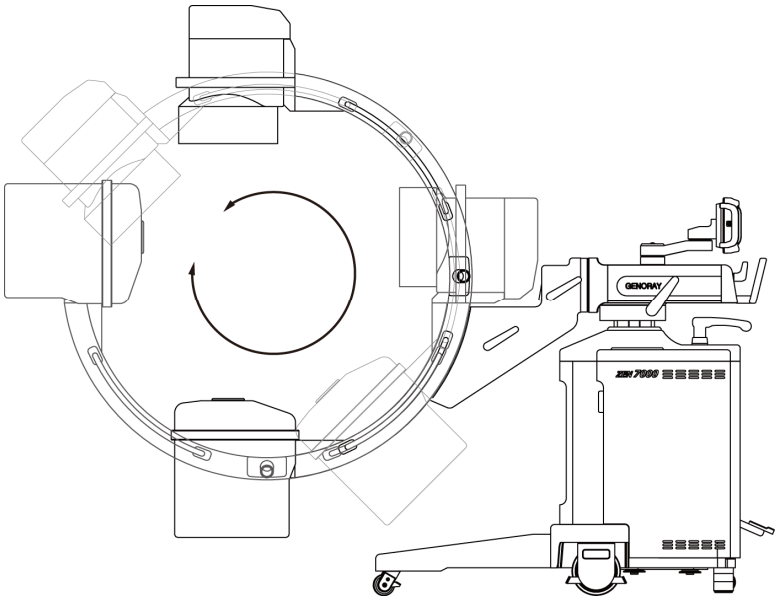


Move C-Arm to the spot you wish to move and fix it with the lever as below.



Rotational motion of the C-Arm could cause serious injury and damage to the unit or to other equipment or personal in the vicinity. Ensure that no persons or objects are within the travel motion of the C-Arm.

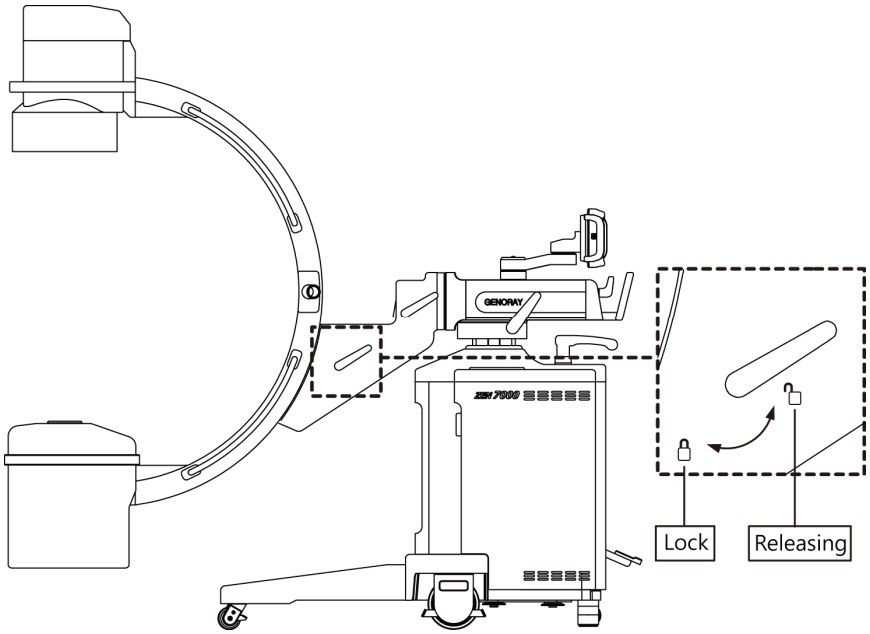
4.1.2 C-ARM Orbital Movement



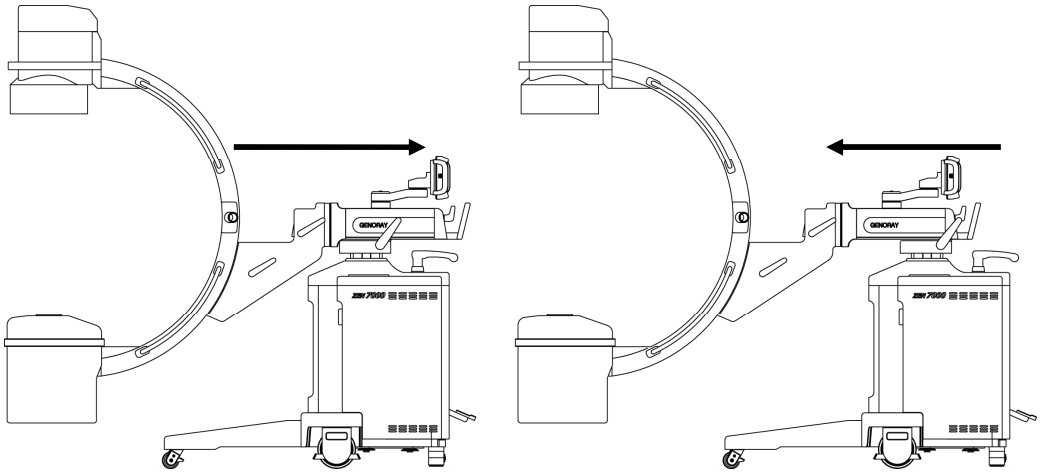
A possible pinch point exists between the C-Arm and the tip of the front cover. Do not place your foot on the tip of the front cover while operating the vertical column or while positioning the C-Arm.

Pinch points exist between the C-Arm support assembly and the C-arm. Do not place fingers or allow clothing in between these assemblies when positioning the C-Arm.

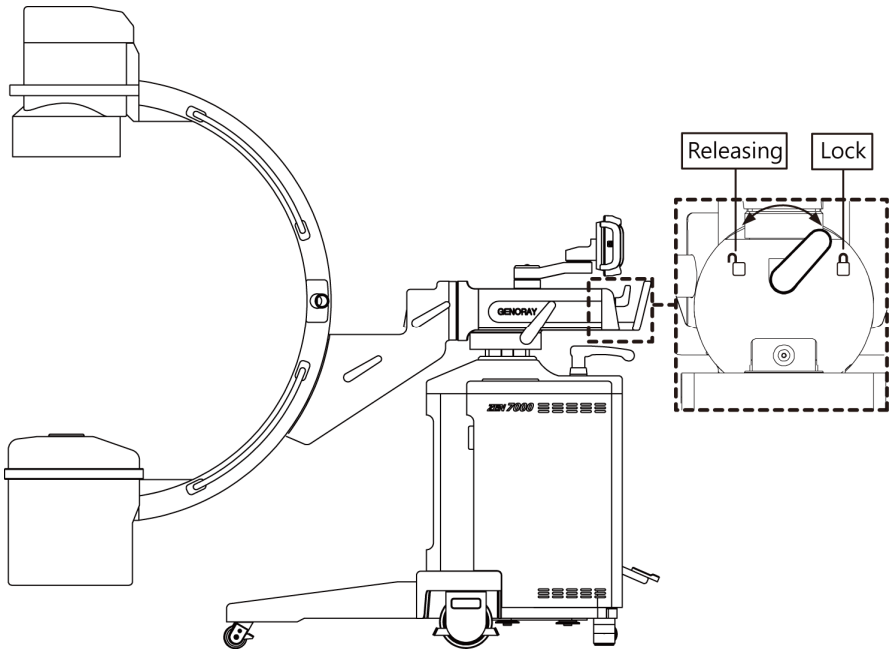
Move C-Arm to the spot you wish to move and fix it with the lever as below.



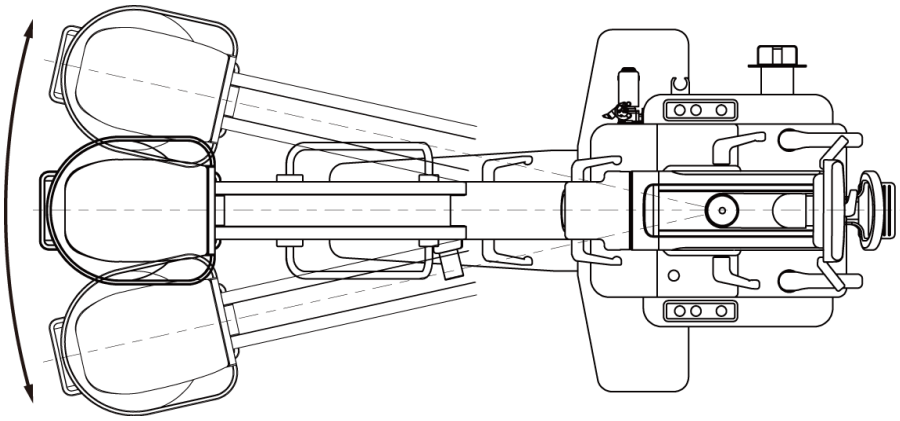
4.1.3 C-ARM Horizontal Movement



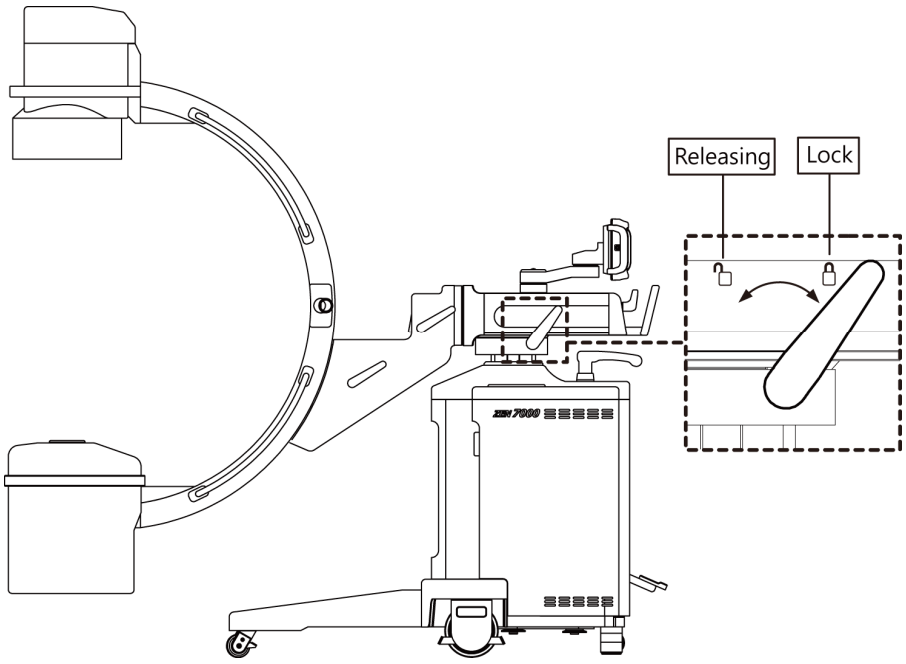
Move C-Arm to the spot you wish to move and fix it with the lever as below.



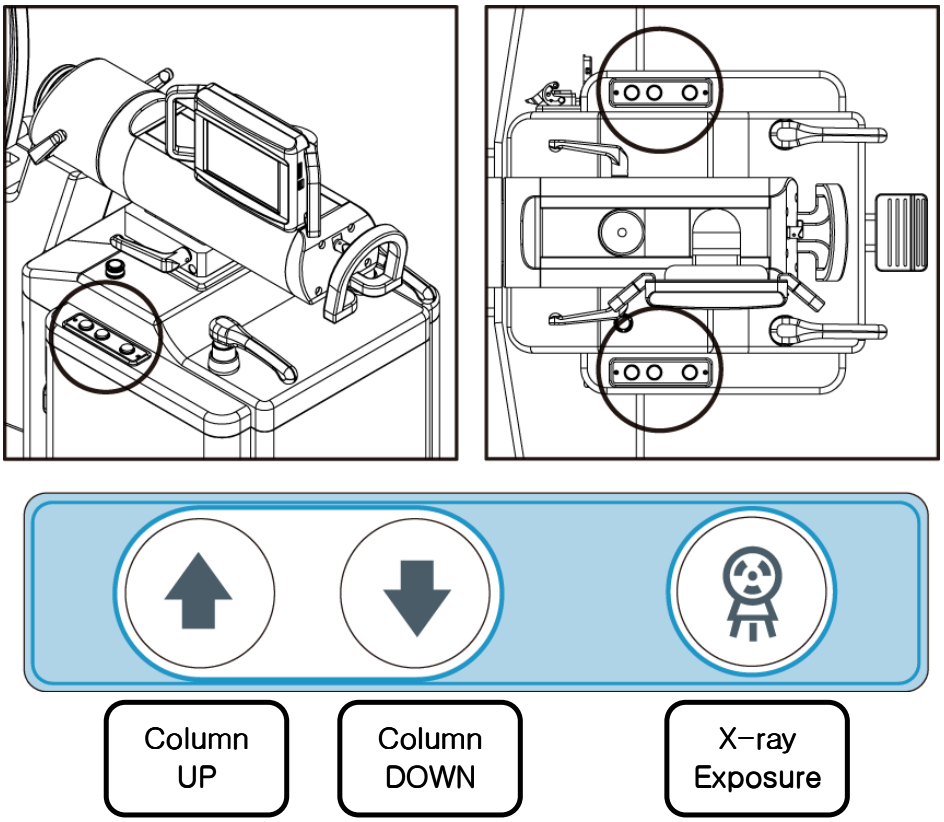
4.1.4 C-ARM Panning



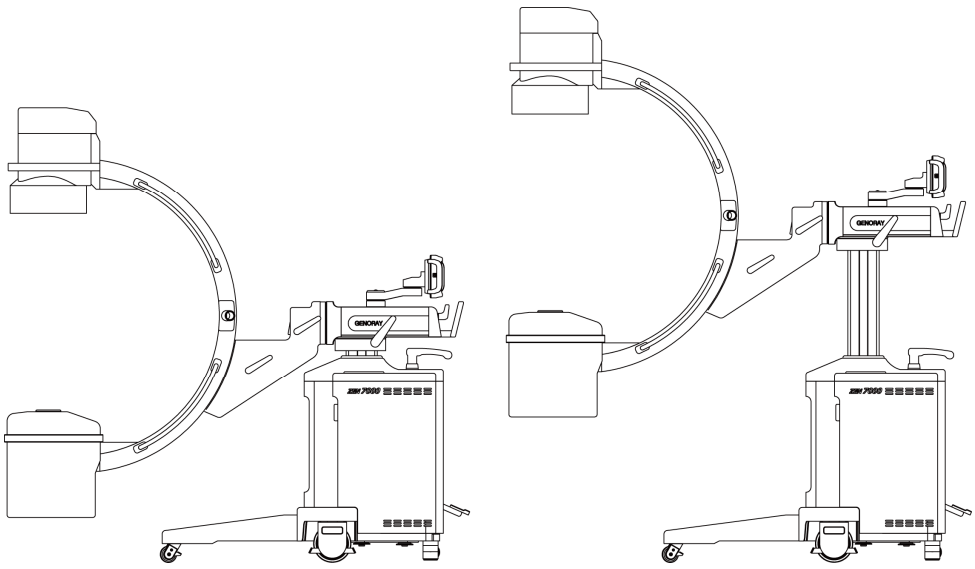
Move C-Arm to the spot you wish to move and fix it with the lever as below.



4.2 Up/Down and X-ray Shooting Button



Lift up/down the C-Arm. C-Arm is moved while the button is pressed. X-ray shooting button is for fluoroscopy.
These buttons are at both sides of C-Arm for user's convenience.



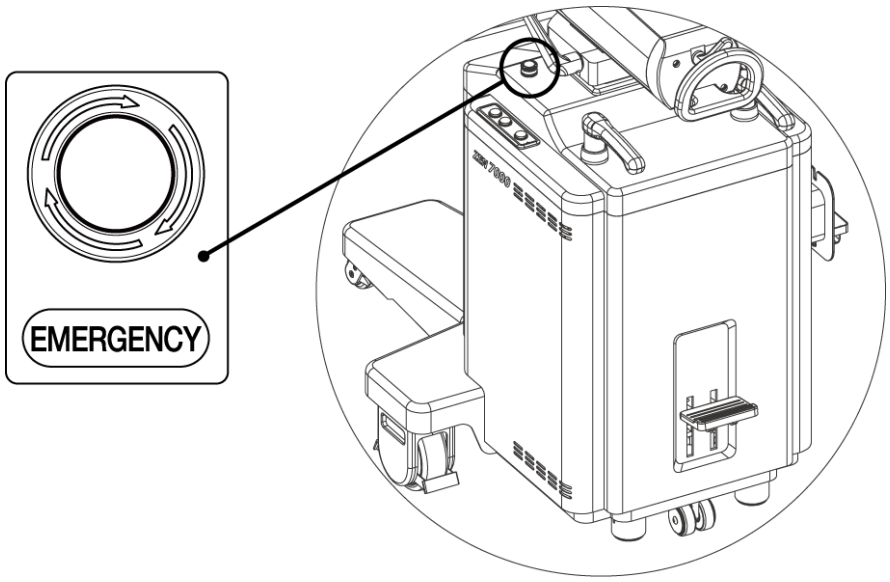
4.3 Collimator Control

By removing the X ray on unnecessary areas, it can prevent the damage of radiation. The controller can be opened / closed while rotating of collimator.)

The processing time between wide open and close is about 15 seconds, and this opening/closing is stopped when it is totally opened/closed.

The processing time for 360° rotation is 25 seconds and rotating is unlimited.

4.4 Emergency



Whole C-Arm operation is stopped when emergency switch is pressed.
To release the emergency, please rotate the switch clockwise.

This switch must be used only for emergency.

4.5 X-ray Exposure Table

Part	Direction	Thickness(Cm)	Distance(Cm)	kVp	mAs	Grid
Skull	A.P.	18	80	70	25	+
	A.P.	20	80	75	25	+
	Lat.	15	80	70	20	+
	Lat.	17	80	70	25	+
Thoracic spine	A.P.	19	80	65	20	+
	A.P.	12	80	70	16	+
	Lat.	26	80	80	25	+
	Lat.	11	80	70	12	+
Lumbar spine	A.P.	19	80	80	25	+
	A.P.	21	80	80	32	+
	Lat.	25	80	100	40	+
	Lat.	28	80	100	50	+
Pelvis	A.P.	19	80	80	25	+
	A.P.	21	80	80	32	+
Shoulder joint		9	80	60	8	-
Humerus		6	80	55	6	-
Hand		2	80	45	3	-
Femur		15	80	65	8	-
Knee joint		12	80	65	10	-
Ankle		7	80	65	6	-
Toes		3	80	50	6	-
Bladder		20	80	80	20	+

Above table is applied to standard mode. Please adjust kV or mA/mAs when the image is not clear.

5. Notice, Safekeeping and Care

5.1 Notice

1) Return operation switch, or dials to original state by fixed steps and turn off the power.
2) Keep accessories or codes after arrange them.
3) Keep clean the machine.
4) Do not try to fix by yourself when the machine is broken, call the authorized technician.
5) Do not remodel the machine.

5.2 Safekeeping

1) Keep away from water.
2) Install machine to the place which has no risk of atmospheric pressure, temperature, humidity, airing, dust, salt, or air with sulfur.
3) Be careful with slant, vibration, or shock.
4) Do not keep the machine in the place which has chemicals or gas.

5.3 Maintenance

1) Machine and parts should be checked by routine maintenance.
2) If the machine is not used for a while, but should be used again, the machine should be inspected by manufacturer.

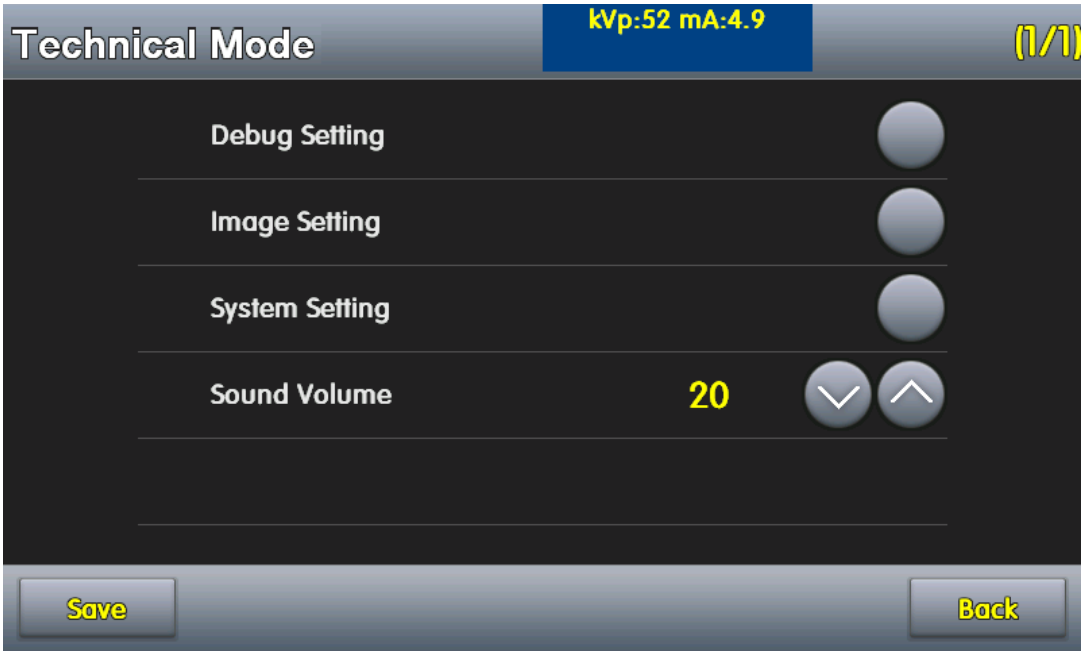
5.4 Cleaning

1) Turn off machine before you clean.
2) Clean machine regularly with neutral detergent and prevent the liquid to go inside the machine.
3) Disinfect the parts which touches patient with antiseptic solution such as 2% ammonia water.
4) Do not use caustic substance for cleaning.

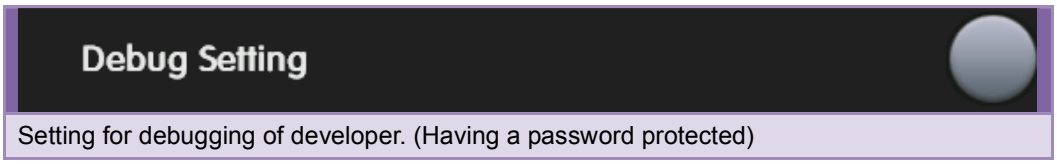
6. Technical Mode

- Push the button on OP for 2~3sec for entrance of Technical mode.
- Off Nr. 5 of Main B/D DIP Switch for entrance of Technical mode.

6.1 1st page of Technical Mode



6.1.1 Debug Setting



Setting for debugging of developer. (Having a password protected)

Function	description
Histogram	Display the Histogram of image on HEM monitor.
DNR Setting	According to the set value, the afterimage and noise is removed.
Use Auto Region	ABC and Auto Histogram is turned on in selecting part of exposure.
KVP Offset	Set the KVP offset. (Volume range : -10 ~ 10)
mA Offset	Set the mA offset. (Volume range : -10~10, 1=0.1mA)
Pulse Width	Set the Pulse count for using the Pulsed mode.
Low Pulse width	Set the Low Pulse count to using the Low pulsed mode.
Large Pulse width	Set the Large Pulse count to using the Large pulsed mode.
User PID	Set the value of PID.
Collimator Setting	Set the Parameter of Collimator.
Use DoseMeter	Set using the dosimeter.
Use Zenis	Set using the Zenis and Mini zenis is opposition to Zenis.
Use Laser	Set using the laser.
Use DSA	Set using the DSA.
Serial Speed High	Set the serial speed. (On: 115400, Off: 34800)
LIH Mode	Mean of “0~50” is time of changing LIVE display when turning on the shot switch. (1 = 50msec, continuous operation to set 22.)

6.1.2 Image Setting

Function	description
Histogram Step	Set the contrast value of image using Histogram Step (range : 0 ~ 9).
Circle Mask	Set for using the Circle Mask on monitor display.
ABC Ref.low	Set the brightness value of Low ABC (range : 1 ~ 150, default value : 65). In the ABC low mode, If the kV value is lower than the standard, ABC Ref.low value is raised than 65. If not, ABC Ref.low value is lowered than 65.
ABC Ref.high	Set the brightness value of High ABC (range : 1 ~ 150, default value : 105). In the ABC high mode, If the kV value is lower than the standard, ABC Ref.high value is raised than 105. If not, ABC Ref.high value is lowered than 105.
ABC Ref.LF	Set the brightness value of Large focus ABC (range : 1 ~ 150, default value : 120). In the Large Focus ABC mode, If the kV value is lower than the standard, ABC Ref.LF value is raised than 120. If not, ABC Ref.LF value is lowered than 120.
Pulse30 ABC Ref.LF	Set the brightness value of Large focus ABC on Pulse 30 mode (range : 1 ~ 150, default value : 120). In the Large Focus ABC Pulse 30 mode, If the kV value is lower than the standard, ABC Ref.LF value is raised than 120. If not, ABC Ref.LF value is lowered than 120.
Pulse15 ABC Ref.LF	Set the brightness value of Large focus ABC on Pulse 15 mode (range : 1 ~ 150, default value : 120). In the Large Focus ABC Pulse 15 mode, If the kV value is lower than the standard, ABC Ref.LF value is raised than 120. If not, ABC Ref.LF value is lowered than 120.
Pulse ABC Ref.SF	Set the brightness value of Small focus ABC on Pulse mode (range : 1 ~ 150, default value : 120). In the Small Focus ABC Pulse mode, If the kV value is lower than the standard, ABC Ref.LF value is raised than 120. If not, ABC Ref.LF value is lowered than 120.
ABC High Mode	Set the Using ABC High mode.
Set ABC	Set the initial value of ABC about of part of exposure.
TCP/IP Setting	Go to TCP/IP Setting mode.

6.1.3 System Setting

Function	description
Use Auto Region	ABC and Auto Histogram is turned on in selecting part of exposure.
Version	Check the version of OP & main controller and the system S/N. OP Version 1.0.0.2009.6.12_B1 MB Version System S/N ABCEFGH
Log View	Display on “Log viewer” [Exposure] Accumulation Time and Count [Body Part] Accumulation Time and Count [Use Time] Installed time and Last use time [Last Error] Last error time [Error Information] Error count ==========[Exposure]========== MODE / Accumulation Time D| H| M| S / Count Total Time 0 00 02 15 2 Continues 0 00 02 15 2 Pulsed 0 00 00 00 0 Radiography 0 00 00 00 0 ==========[Body Part]========== Part / Accumulation Time D| H| M| S / Count Hand 0 00 01 26 1 Thoracic 0 00 00 48 1 Femur 0 00 00 00 0 Spine 0 00 00 00 0 ==========[Use Time]========== InstallTime 2009-09-14 18:03:26 LastUseTime 1969-12-31 16:00:00 ==========[Last Error]========== 2009-09-14 18:03:26 Error0
Upgrade op	Copy OP.exe in the “UpgradeOP” folder of the USB Memory.
Pivot	Horizontal display of landscape in Setting default and Vertical display of landscape in Setting of Default
Use VGA	Set the Output of LIH&LIVE signal or HEM.
Sound Mode	Set the sound. (range : 0~9) Choose the mode that change sound when X-ray exposure.
Set Install Time	Save the Install time.
Set System Time	Set the system time.
Use Native	Set the language.

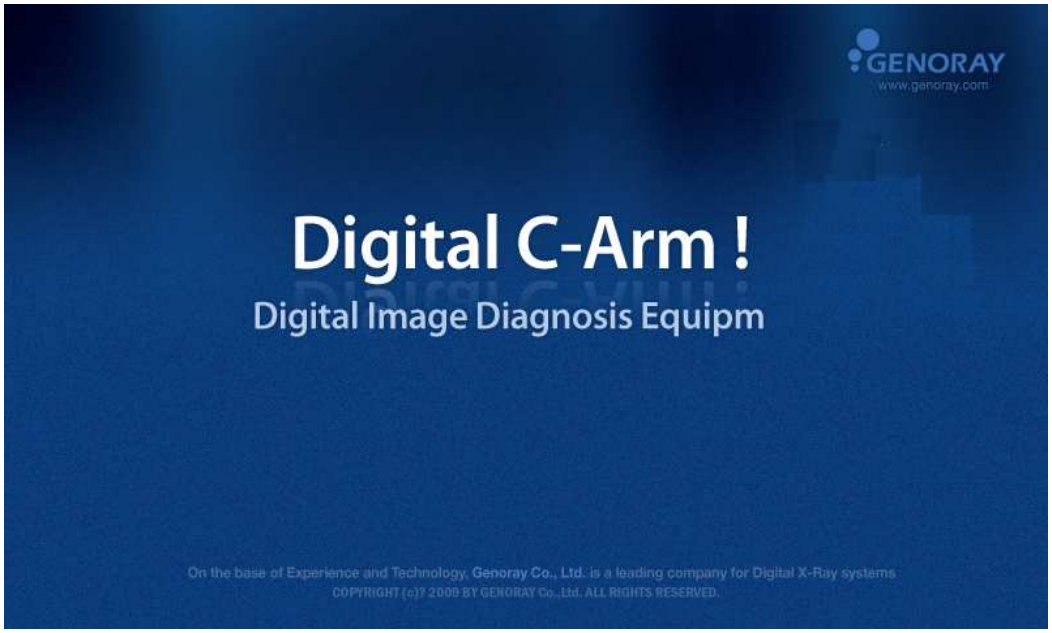
6.1.4 Sound Volume

Set the sound volume of OP (range : 1 ~ 150, default value : 120).

If adjusted volume is not right, machine might not be worked.

Temperature Warning sign

OP Logo screen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Digital Image Diagnosis Equipm
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7. Image Storage Device – Mini Zenis (Option)

The image received from ZEN-7000 is stored efficiently.

7.1 Patient List

7.1.1 Equipment status

Status of PC Connection	Status of SD Card Connection	Status of USB Connection

7.1.2 Patient Registration

Patient registration

7.1.3 Memory Conversion

Select the storage devices : SD Card or USB

7.1.4 Save patient

Save all the patients of the list.

Button is pressed, the following screen will appear.

USB : All patient images and information stored on USB.

TCP : All patient images and information stored on ZENIS.

7.1.5 List Conversion

Go to the previous list of patients

Go to the next list of patients

7.1.6 Patient Management

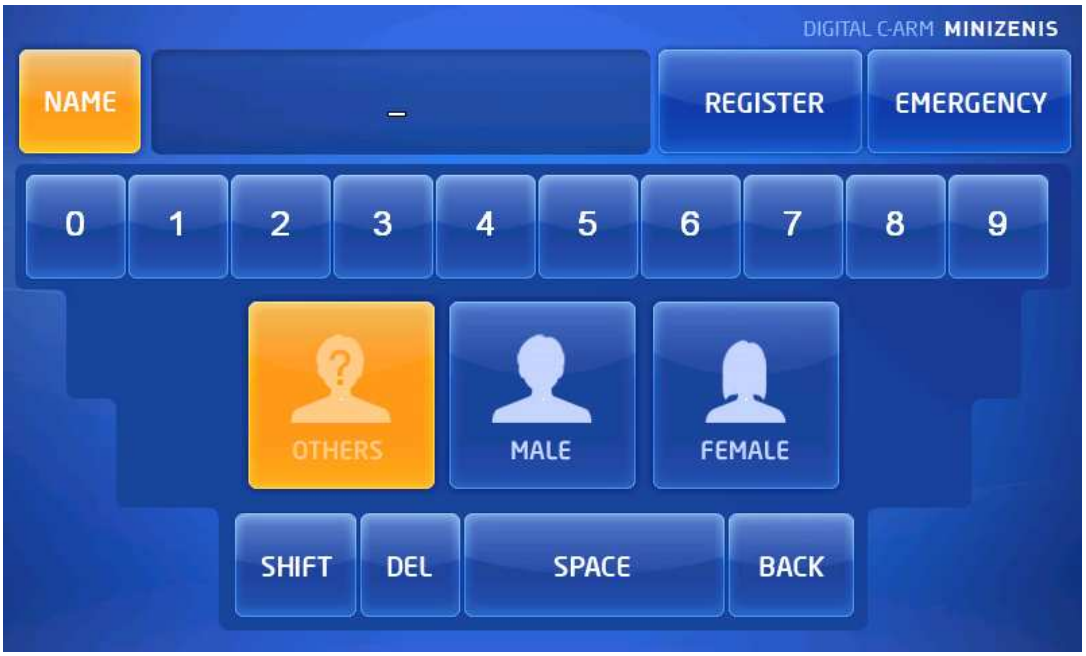
When you select a patient, it is shown below.

Open the patient

Delete all images and information of the patient

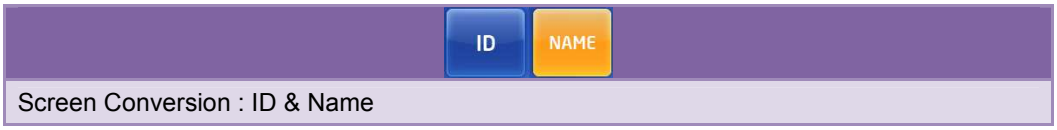
7.2 Patient Register

<Enter the name of the patient>



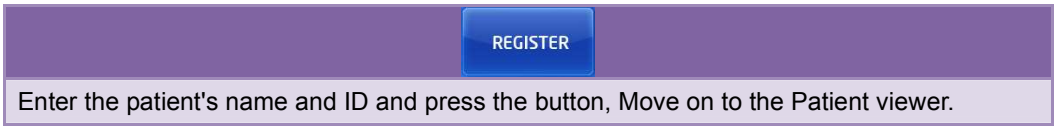
<Enter the ID of the patient>

7.2.1 Screen Conversion



Screen Conversion : ID & Name

7.2.2 Register



Enter the patient's name and ID and press the button, Move on to the Patient viewer.

7.2.3 Emergency

Does not enter the patient's name and ID and press the button, Move on to the Patient viewer.

7.2.4 Shift

Character case conversion (Upper/Lower)

7.2.5 Del

Delete entered characters

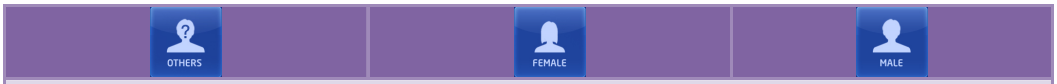
7.2.6 Space

Enter a space

7.2.7 Back

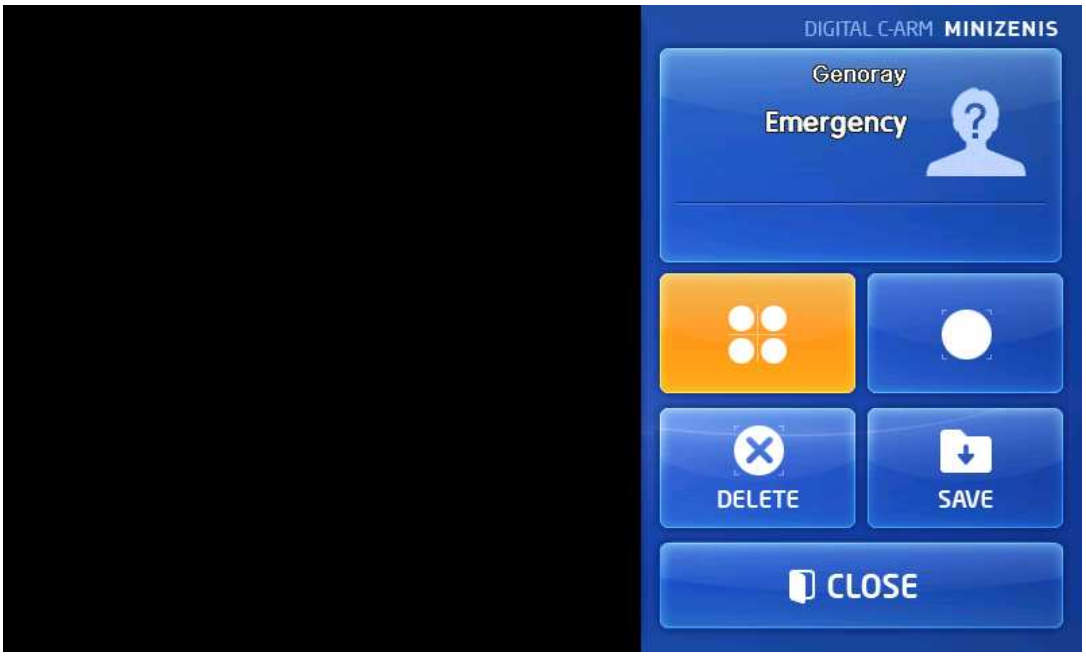
Go to the list screen of patients.

7.2.8 Gender of the patient



Choose the gender of the patient

7.3 Patient Image Mode



7.3.1 Split Screen

Display the 4 images	Display the 1 image

7.3.2 Delete

Delete image

7.3.3 Save

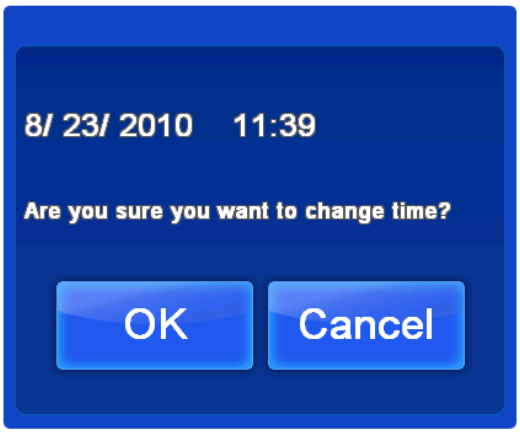
Save image

7.3.4 Close

Close the patient image

7.4 Time Setting

This mode of Mini Zenis can set the date and time.



< Screen of the change question>

< Screen settings>

8. Error Message and Condition/Process Message

Error messages are as below.

These messages occur on main screen of X-Ray controller when machine is not working well for any reason.

Error _ code	Display	Reason		Action
ERR_CODE 01	EP_ERR	kV output is too low		Call for after-sales service
ERR_CODE 02	IP_FLU_ERR	mA output is too low (Fluoroscopy)		Call for after-sales service
ERR_CODE 03	IP_FILM_ERR	mA output is too low (Radiography)		Call for after-sales service
ERR_CODE 04	mAs_ERR	mAs output is too low (Radiography)		Call for after-sales service
ERR_CODE 07	THERMAL_SW_ERR	TANK overheated	TANK is overheated	Leave machine for an hour and try to use
			The others	Call for after-sales service
ERR_CODE 08	EM_SW_ERR	Emergency	Emergency switch is pressed	Release the emergency switch
			The others	Call for after-sales service
ERR_CODE 09	FOOT_SW_ERR	Foot switch is pressed when power is turned on	Foot switch is pressed	Reset machine
			The others	Call for after-sales service
ERR_CODE 10	SHOT_SW_ERR	Shooting button is pressed when power is turned on	Shooting button is not pressed	Reset machine
			The others	Call for after-sales service
ERR_CODE 11	READY_SW_ERR	Ready button is pressed when power is turned on	Ready button is pressed	Reset machine
			The others	Call for after-sales service
ERR_CODE 13	VD_SIG_ERR	Camera signal has problem		Call for after-sales service
ERR_CODE 14	RAD_ABORT_ERR	Switch is released when exposure in film mode.		Reset machine
ERR_CODE 15	INVERTER_ERR	X-ray inverter fail.		Reset machine
ERR_CODE 16	ROTOR_ERR	Rotor B/D start_OK signal has problem		Call for after-sales service
ERR_CODE 17	FILRDY_ERR	Filament Ready Signal of Filament B/D has problem		Call for after-sales service
ERR_CODE 18	M_OVER_ERR	Torque is occur too highly than setting mA of Motor Inverter		Call for after-sales service

9. Specification

9.1 Basic Specification

■ Input

Line Voltage	AC 220-230V AC 100-120V (USA)
Input Power	4kVA
Line Frequency	50 / 60 Hz

■ Output

- Radiography

Output volume	120kV, 20mA(Fixed)
Tube Voltage Range	40kV ~ 120kV, Step: 1kV
mA range	0.4mAs ~ 100mAs, 24 Steps

- Fluoroscopy

Output volume	120kV, 6mA
Tube Voltage Range	40kV ~ 120kV, step: 1kV
Tube electric current range	0.2mA ~ 6.0mA, step : Continuity

■ Filtration : X-ray Tube assembly : 1.4mmAl, Add in device enclosure : 3.0mmAl
Total filtration : 4.4mmAl

■ Anode Heat Storage Capacity: 300kHU (225 kJ)

9.1.1 Grouping

- Class I equipment (as defined by IEC 60601-1)
- Class IIb according to guideline 93/42/EEC
- Type B applied part (X-ray generator)
- Ordinary equipment (IPX0) with foot switches (IPX8)
- Equipment not suitable for use in the presence of a flammable an aesthetic mixture with air or with oxygen or nitrous oxide.

9.1.2 Regulatory Compliance

ZEN-7000 was tested and found to comply with the following IEC international standards and regulations:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-3
- IEC 60601-2-7
- IEC 60601-2-28
- IEC 60601-2-32

9.1.3 X-RAY Collimator

Operation	Manual / Remote Motor Drive
Constructions	Lead Shutters
Speed	Rotation : 360° / 25sec Long & Cross : 15sec.(Open-close)
Aperture	Round 14.8 mm for 8" x 10" Cassette
Accuracy	2% OF SID In Use

9.1.4 X-Ray Tube

1. Tube Name: IAE RTM 70H
2. Electrical Data

Circuit	DC (Center Grounded)
Operating Tube Voltage	40 to 120 kV
Focal Spot	L: 0.6 mm, S: 0.3 mm
Input Energy	L: 25KW, S: 6KW

3. Mechanical Data

Dimension	Overall Length : 99 mm Max. Tube Diameter : 95 mm
Target Angle	10 Degrees
Inherent Filtration	0.7 mm A1 Equivalent (IEC 522)
Input Energy	L: 25KW, S: 6KW
X-Ray Coverage	350 mm x 350 mm AT SID 1000 mm 250 mm x 250 mm AT SID 700 mm
Cooling Method	Oil Immersed (60℃ MAX.)

4. Maximum and Minimum Ratings

Max. Tube Voltage	130kV
Min. Tube Voltage	40Kv
Filament Current	L: 5.4A, S: 5.0A
Max. Current	Large: 60mA, Small:15mA

9.1.5 X-Ray Generator

1. Input

Line Voltage	230 Vac ±10% / 1 Phase
Output Power	5 kW
Line Frequency	50 / 60 Hz

2. Output

- Short time rating

Output volume	120kV, 20mA(Fixed)
Tube Voltage Range	40kV ~ 120kV, Step: 1kV
mA range	0.4mAs ~ 100mAs, 24 Steps

- Long time rating

Output volume	120kV, 6mA
Tube Voltage Range	40kV ~ 120kV, step: 1kV
Tube electric current range	0.2mA ~ 6.0mA, step : Continuity
Time adjustment	0 ~ 5 minutes alarm signal

3. Dimension & Weight

Dimension	145(W) X 255(H) X 325 (D)
Weight	About 20Kg

9.1.6 X-Ray Support Part

SID	1000 mm
SSD	200mm
Orbit. Rotation	120 Degrees
Horiz. Travel	200 mm
Vert. Travel	500 mm
Wigwag. Travel	±12.5 Degrees
Rotation	±190 Degrees

9.1.7 Image Intensifier

Type	E5830SD-P4A
Performance	
- Central Resolution (Lp/cm)	N: 52 M1: 58 M2: 68
- Conversion Factor (N Mode)	45 ((cd/m^2) / (uGy/s)) 390 ((cd/m^2) / (mR/s))
- Contrast Ratio (N Mode)	30:1 (10% Area Contrast) 19:1 (10mm Dia. Contrast) DQE (IEC Standard): 65%

Mechanical Data	
- Overall Length	338±5 mm
- Max. Diameter	Φ304±2 mm
- Normal Entrance Field Size	N Mode : 230mm (9") M1 Mode : 160±5 mm (6") M2 Mode : 120±5 mm (4.5")
Output Image Diameter	25±0.5 mm
Weight (Approx.)	22Kg
Power Supply	
- Input Voltage	24±1 Vdc
Operating Environmental	
- Temperature	5 ~ 40℃
- Humidity	30~85%
- Pressure	70~106 kPa

9.1.8 Camera

Effective Pixel	1004 (H) X 1004 (V)
Scanning system	1004 X 1004, 30 f/s, 40 MHz, Progressive
Frequency	Horizontal : 31 KHz, Vertical : 30 KHz
Resolution	H : 1000 TV lines, V : 1000 TV lines
Dynamic Range	More than 60 dB

9.1.9 Environmental

Operating Environmental	
- Temperature	+10℃ ~ +40℃
- Humidity	30%~75%RH
Storage Environmental	
- Temperature	-40℃ to +70℃
- Humidity	10%~100% RH

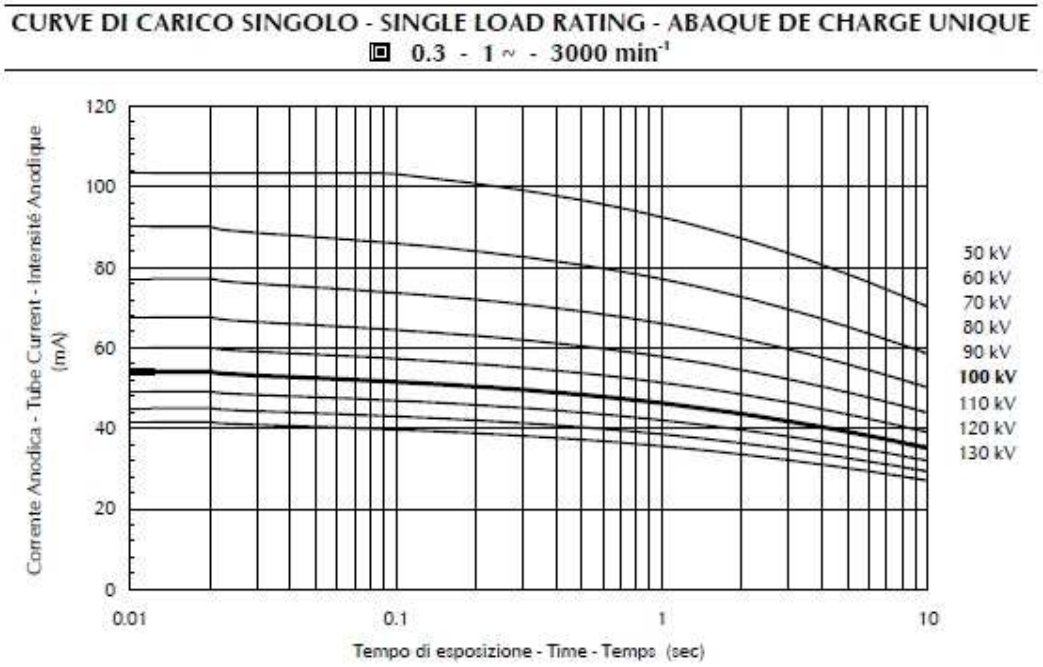
9.1.10 Overall Size and Weight

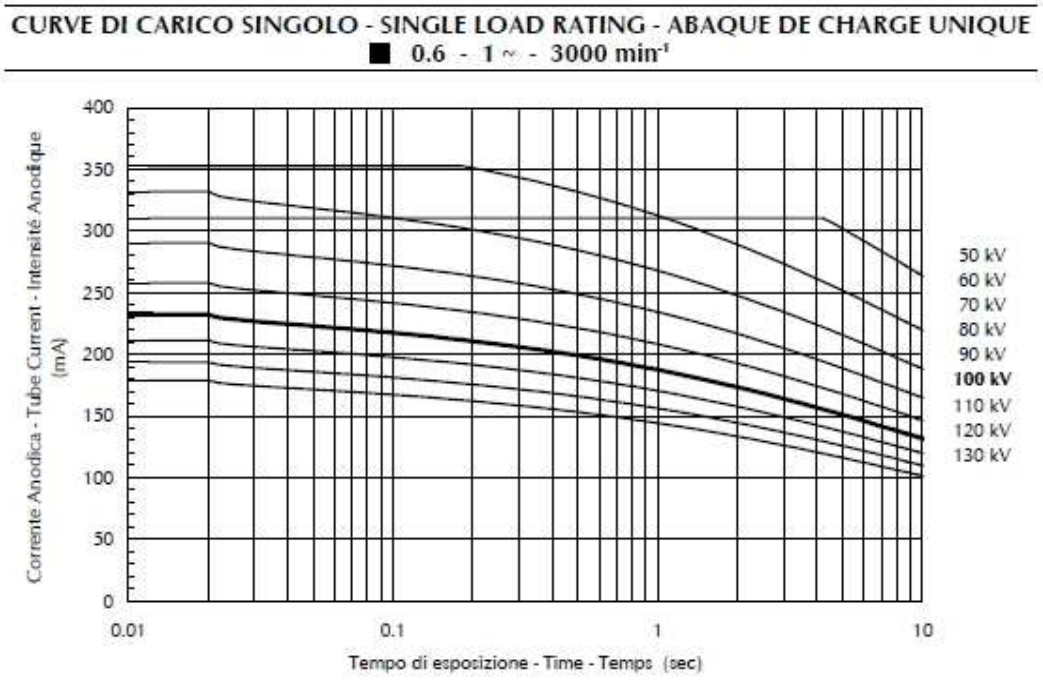
Height	2230 x 1142mm
Width	780 mm
Weight	275kg ± 5%

9.1.11 Image Storage Device

OS	WinCE core 5.0
CPU	MMSP2++
RAM	128Mbyte
Nand	64Mbyte
USB	1.1
Host	10Mbps
LAN	4GB built-in
SD Card	Touch Screen 7Inch (800*480)
Sound	Mono
Language	English
Version	1.0.1.2011.4.11_B1

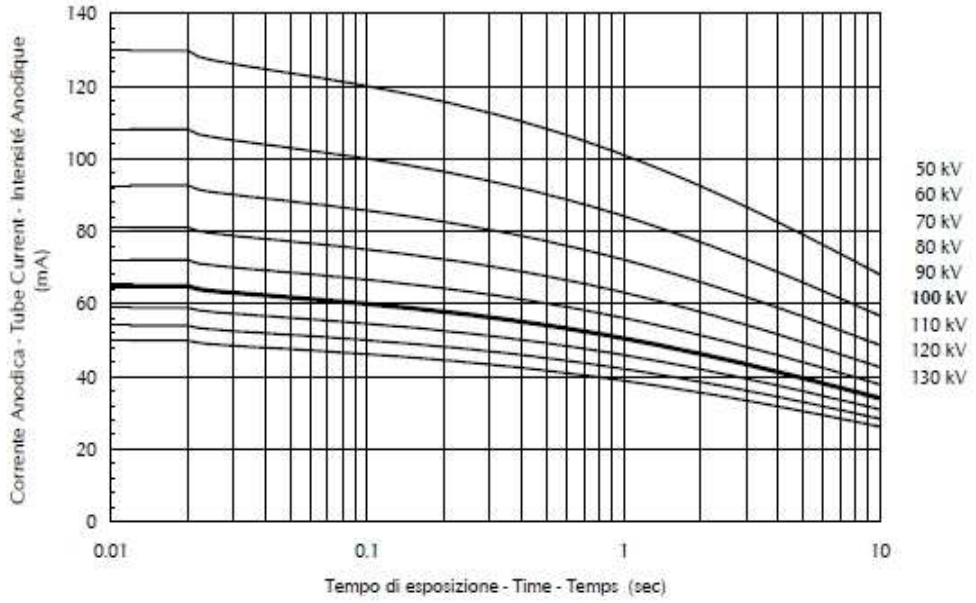
9.2 Character of X-Ray





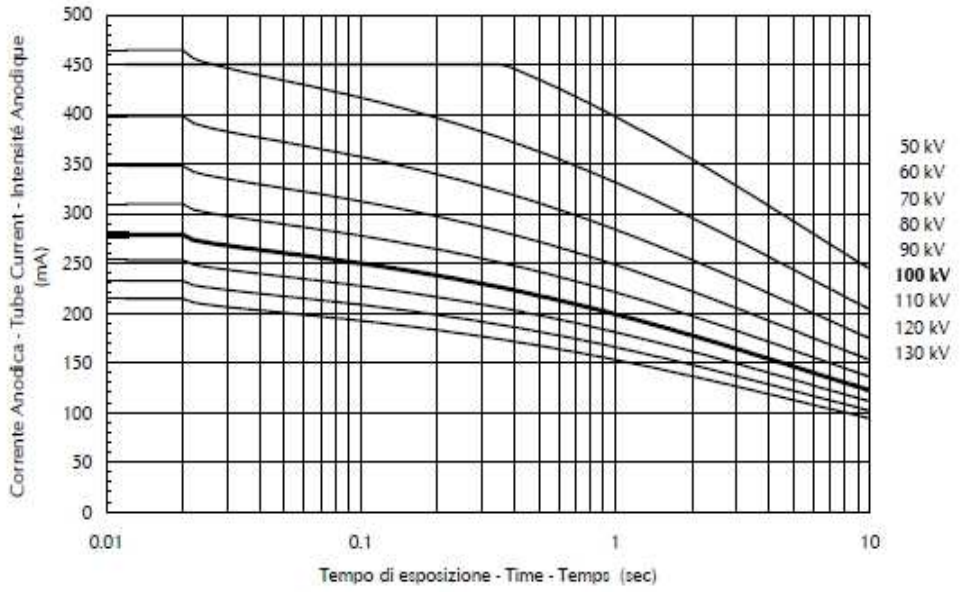
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

▣ 0.3 - 3 ~ - 3000 min^{-1}

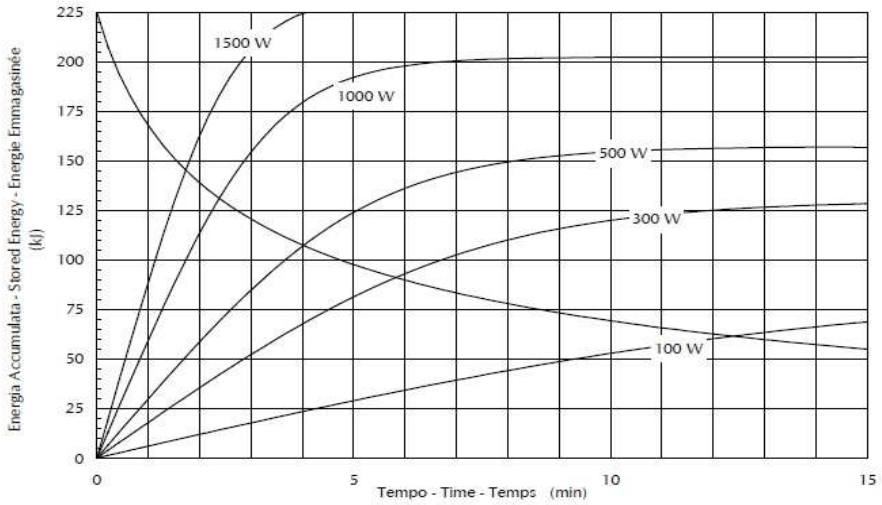


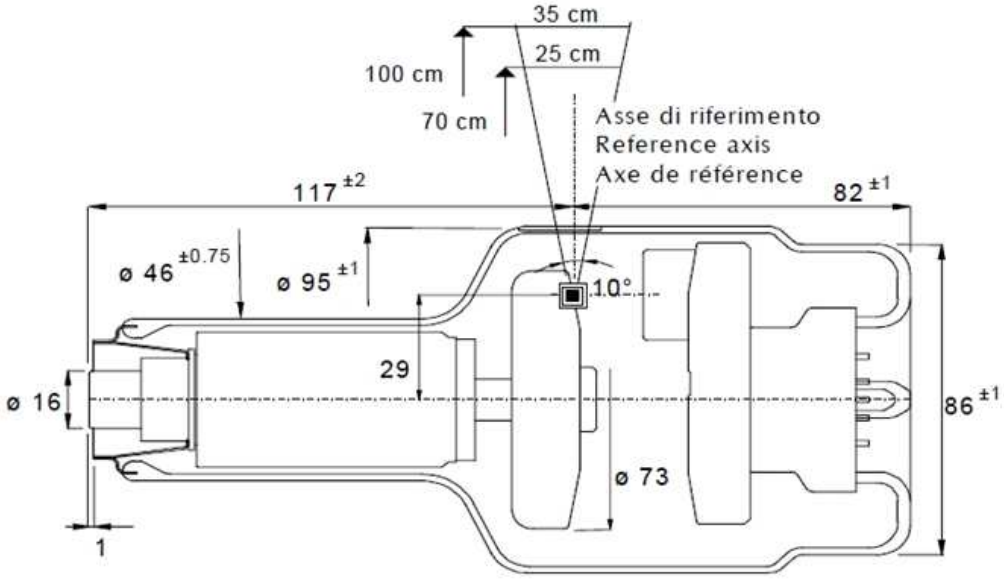
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

■ 0.6 - 3 ~ - 3000 min^{-1}



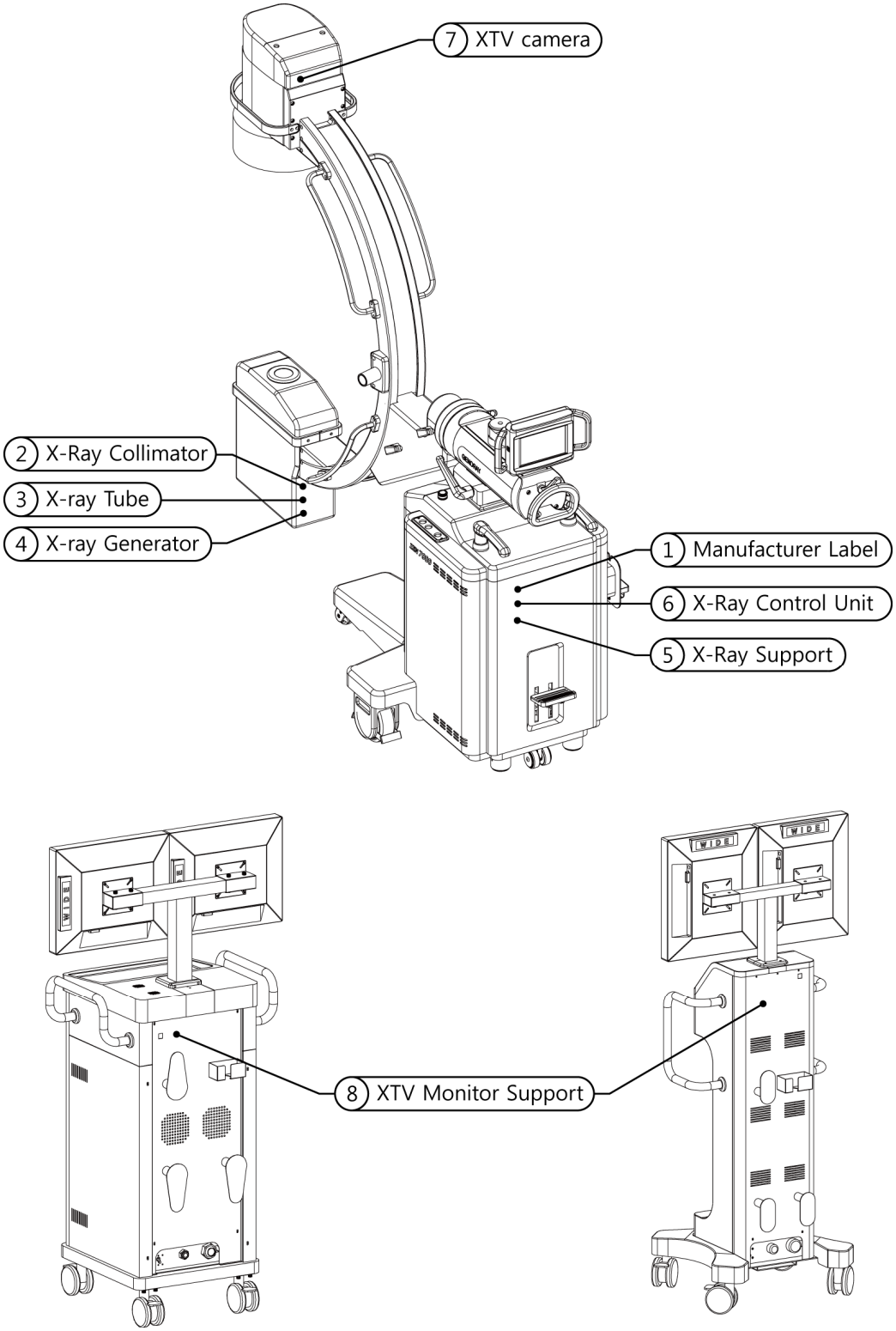
Curve di riscaldamento e raffreddamento dell'anodo
Anode heating and cooling curves
Courbes d'échauffement et de refroidissement de l'anode





9.3 Label

Turn on the machine after checking labels and manual.



□Manufacturer Label

For AC100~120V

1) Product name: Fluoroscopic X-ray system
2) Model: ZEN-7000
3) SN **4)**
5) Input Voltage: AC 100-120V, 50/60Hz, Single Phase, 4kVA
6) Max. Power Rating: Radiography: 120kV, 20mA / Fluoroscopy: 120kV, 6mA
7) Max. Tube Voltage: 130kV
8) Focal Spot Size: 0.3mm / 0.6mm
9) Filtration: Inherent : 0.7mmAl, Total: 4.4mmAl
10) Waiting Time between Two Exposure: 10min

CAUTION-See accompanying documents

11) GENORAY Co., Ltd
#512 Byucksan Technopia 434-6, Sangdaewon 1-Dong, Jungwon-Gu,
Seongnam-City, Gyeonggi-Do, 462-716 KOREA
Tel: + 82-31-737-8020 / Fax: + 82-31-737-8025
GENORAY America Inc.
1073 N. Batavia St. Orange, CA 92867
Tel: 714-289-8020 Fax: 714-453-9661

For AC220~230V

1) Product name: Fluoroscopic X-ray system
2) Model: ZEN-7000
3) SN **4)**
5) Input Voltage: AC 220-230V, 50/60Hz, Single Phase, 4kVA
6) Max. Power Rating: Radiography: 120kV, 20mA / Fluoroscopy: 120kV, 6mA
7) Max. Tube Voltage: 130kV
8) Focal Spot Size: 0.3mm / 0.6mm
9) Filtration: Inherent : 0.7mmAl, Total: 4.4mmAl
10) Waiting Time between Two Exposure: 10min

CAUTION-See accompanying documents

11) GENORAY Co., Ltd
#512 Byucksan Technopia 434-6, Sangdaewon 1-Dong, Jungwon-Gu,
Seongnam-City, Gyeonggi-Do, 462-716 KOREA
Tel: + 82-31-737-8020 / Fax: + 82-31-737-8025
EC REP **Obelis s.a.**
Boulevard Général Wahis 53, 1030 Brussels, BELGIUM
Tel: +32-2-732-59-54 Fax: +32-2-732-60-03

②X-ray Collimator

X-ray Collimator
1. Model : ZIC-300
2. Manufacturer
   : GENORAY Co., Ltd. / KOREA
3. Output : 120kV
4. Material : 3.0 mmPb
5. Serial No. :

③X-ray Tube

X-ray Tube
1. Model : RTM 70H
2. Manufacturer : I.A.E / ITALY
3. Max. Tube Voltage : 120 kV
4. Serial No. :

④X-ray Generator

X-ray Generator
1. Model : HF1 R/28
2. Manufacturer : PSM (ITALY)
3. Input voltage
   :AC230V±10%, 50/60Hz, 5kW
4. Max. Power Rating
   1) Radiography : 120 kV, 20mA
   2) Fluoroscopy : 120 kV, 6mA
5. Serial No. :

⑤X-ray Support

X-ray Support
1. Model : JC-7000A
2. Manufacturer
   : GENORAY Co., Ltd. / KOREA
3. Size (W x H x D)
   : 780 x 2230 x 1142
4. Serial No. :

⑥X-ray Control Unit

X-ray Control Unit
1. Model : JC-7000C
2. Manufacturer
   : GENORAY Co., Ltd. / KOREA
3. Power Requirement
   AC 220V, 50/60Hz, Single phase
4. Output
   1) Radiography :40-120kV, 0.4-100mAs
   2) Fluoroscopy : 40-120kV, 0.2-6mA
5. Serial No. :

⑦XTV Camera

XTV Camera
1. Model : Xynergy
2. Manufacturer
   : GENORAY Co., Ltd. / KOREA
3. Effective Pixel :1004(H)*1004(V)
4. Serial No. :

⑧XTV Monitor Support (Option 1)

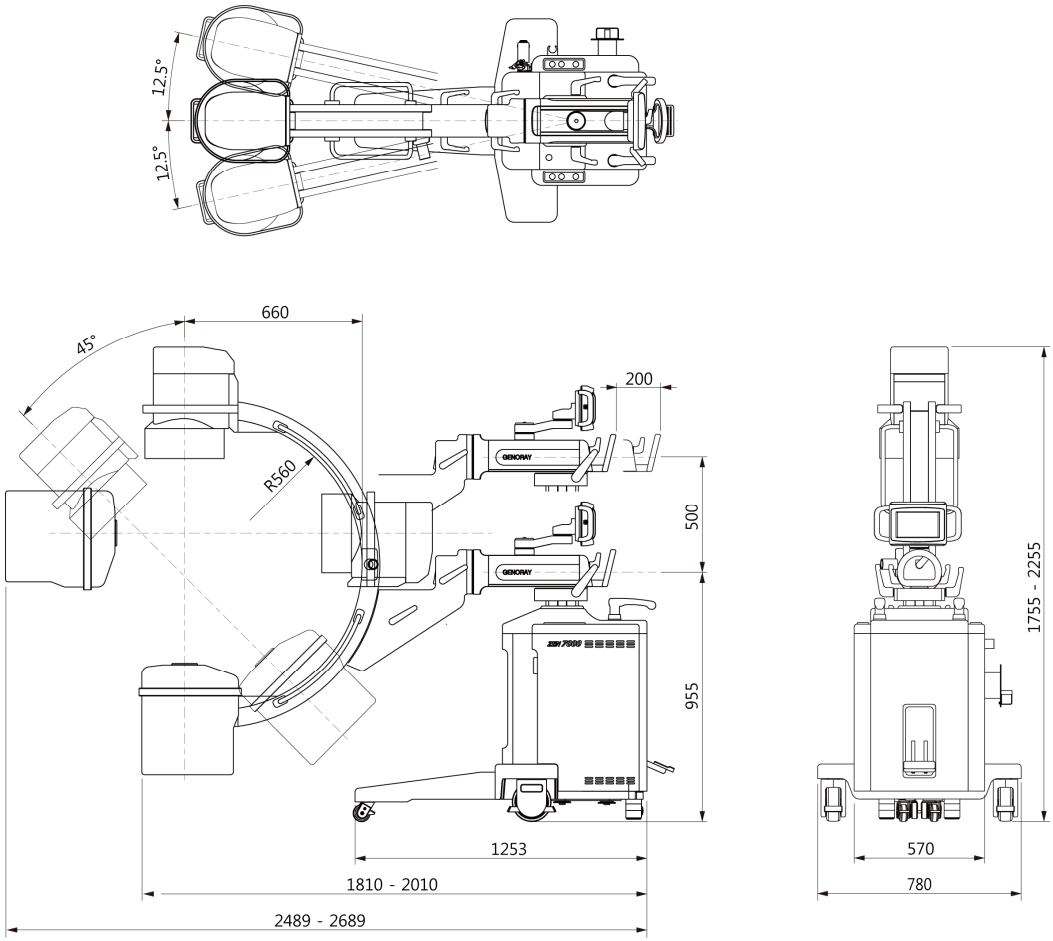
XTV Monitor Support
1. Model : ZEN-CART-05
2. Manufacturer
   : GENORAY Co., Ltd. / KOREA
3. Size (W*H*D mm) :554*1483*541
4. Serial No. :

⑧XTV Monitor Support (Option 2)

XTV Monitor Support
1. Model : S-Troy
2. Manufacturer
   : GENORAY Co., Ltd. / KOREA
3. Size (W*H*D mm) :728*1207*728
4. Serial No. :

9.4 Dimensions

1) Unit: mm, Net weight 275 kg ± 5%



EC Declaration of Conformity

Manufacturer : GENORAY Co., Ltd.

#512 Byucksan Technopia 434-6 Sangdaewon 1-Dong, Jungwon-Gu, Seongnam-City, Gyeonggi-Do, 462-716, KOREA

European Authorized Representative :

Obelis s.a.
Boulevard Général Wahis 53, 1030 Brussels, BELGIUM
Tel: +(32) 2 7325954 Fax: +(32) 2 7326003
E-Mail : mail@obelis.net

GMDN Code : 33139
Device name : Fluoroscopic X-ray System
Model name : ZEN-7000
Multiple Model name : ZEN-5000, ZEN-3090, Ultra-3090 1M, ZEN-3090 1M, ZEN-3090Pro, ZEN-CX3090

Complied Standards

EN 60601-1-2:2007,
EN 60601-1: 1990 + A1: 1993 + A2: 1995
EN 60601-1-3:1994, EN 60601-2-7:1998, EN 60601-2-28:1993
EN 60601-2-32:1994

Classification : Class IIb by Rule 10 of Annex IX, MDD 93/42/EEC as amended by 2007/47/EC

Conformity Assessment Route : Annex II excl. section 4, MDD 93/42/EEC as amended by 2007/47/EC

We(Genoray) hereby declare that the ZEN-7000 complies with the Medical Device Directive 93/42/EEC as amended by 2007/47/EC (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) using Annex II excl. section 4 as the conformity assessment procedure via DNV(Det Norske Veritas Certification AS, Veritasveien 1, 1322 HOVIK, Norway , NB No. : 0434) as the Notified Body..

Place, Date of issue : Seoul, Korea May 24th 2010
Signature :

President
on behalf of GENORAY Co., Ltd.

CE
0434

GENORAY

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